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# USAID Health-Related Research and Development Progress Report

An Update on the 2011–2015  
Health Research Strategy



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**An Update on the 2011–2015  
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In the last two decades, the world has made unprecedented progress in global health. Because our development efforts harness research, innovation, science, and technology, the global rates of child mortality, chronic hunger, and extreme poverty were cut in half. Each day this year, 17,000 more children will live past their fifth birthday, and 700 more women will survive childbirth compared to 1990.

In global health, research and development advances our efforts to end preventable child and maternal deaths, achieve an AIDS-free generation, and keep the world safe and secure from infectious diseases and emerging threats. I am pleased to introduce the **U.S. Agency for International Development's (USAID's) 2014 Health-Related Research and Development Progress Report**. Guided by a multiyear health-related research strategy, USAID is using entrepreneurial insight and scientific and public health expertise, to solve some of the most pressing challenges of our time. Research and innovation helped eradicate smallpox and launch the Green Revolution. It is with this spirit of innovation and focused investment in science and technology that we will be able to accelerate progress in global health by bending the curve of development.

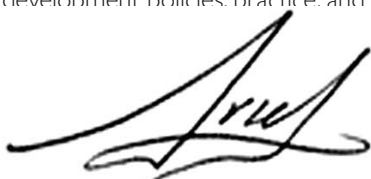
USAID's global health research and development portfolio includes investments in more than 100 technologies in various stages of development. USAID's global health research team works closely with partners within the Agency, including the U.S. Global Development Lab, Grand Challenges for Development, Development Innovation Ventures, and the Partnerships for Enhanced Engagement in Research (PEER) program, to drive science and technology that can transform development challenges. Because the rapid economic transition in many of our partner countries demands greater analytic sophistication on economics and health financing, we have built up a critical mass under our new Chief Health Economist to help mobilize domestic resources to supplement and sustain our investments.

U.S. investments in research and innovation have led to critical breakthroughs in prevention, diagnosis, and treatment of deadly global diseases. Building on a strong tradition of evidence for sound decisions in global health, we advanced a very low-cost antiseptic used to prevent umbilical cord infections in newborns; developed and tested new products to protect women against HIV and unintended pregnancy; supported and delivered a new test that can quickly diagnose drug-resistant tuberculosis; and advanced a neonatal resuscitator that delivers more volume, prevents air leakage, and has easier assembly and disassembly. Advances in mobile technology are leading to a new generation of mobile health tools that will dramatically increase access to healthcare. Advances in genomics mean that scientists can track diseases on a molecular level, allowing them to identify outbreaks, understand patterns of disease transmission, and develop targeted drugs and vaccines. An upcoming 2015 Summit on Measurement and Accountability for Results in Health, co-convened by USAID, WHO and the World Bank, will develop a global roadmap for results and accountability in the post-2015 era.

Since the 2012 Child Survival: Call to Action summit and the 2013 Lancet Commission on Investing in Health, the feasibility of ending preventable child and maternal deaths by 2030 has been validated by a growing technical consensus. In June 2014, USAID and UNICEF with the governments of Ethiopia and India and the Bill & Melinda Gates Foundation convened Acting on the Call: Ending Preventable Child and Maternal Deaths to align all actors around country plans and to maximize results. However, even with economic growth and sustained official development assistance, many poor countries will not be able to accommodate the current package of life-saving interventions. For that, we will need both improved health systems performance and a continued supply of life-saving innovations, both of which benefit from research and implementation science.

The Ebola epidemic in West Africa makes clear that our global efforts to build the capacity to prevent, detect, and rapidly respond to infectious disease threats have never been more vital. Much like cholera preys on weak water systems after a disaster, Ebola is preying on a weak public health system after years of conflict and upheaval in Liberia, Guinea and Sierra Leone. In response to the Ebola outbreak, USAID is partnering with the White House Office of Science and Technology, the U.S. Centers for Disease Control and Prevention, and the Department of Defense to launch Fighting Ebola: A Grand Challenge for Development, which will provide healthcare workers in Ebola-affected countries the personal protective equipment they need on the front lines.

The challenge before us now is not only to sustain our progress, but also to deepen and accelerate our efforts. Answering President Barack Obama's call to end extreme poverty and its most devastating corollaries, including widespread hunger and preventable child and maternal deaths, will advance mankind. Informed by cutting-edge evidence and analysis, we are identifying the most promising opportunities in health research from early stage research and assessment to field implementation and use. Along this continuum, evidence informs development policies, practice, and strategy.



Ariel Pablos-Méndez

Assistant Administrator, Bureau for Global Health  
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# Acronyms and Abbreviations

ART	Antiretroviral therapy
bCPAP	Bubble continuous positive airway pressure
bNAb	Broadly neutralizing antibody
CAPRISA	Centre for the AIDS Programme of Research in South Africa
CHX	Chlorhexidine
CII	Center for Accelerating Innovation and Impact
CMAM	Community-based management of acute malnutrition
CSHGP	Child Survival and Health Grants Program
DPV	Dapivirine
EPCMD	Ending preventable child and maternal deaths
FACTS	Follow-on African Consortium for Tenofovir Studies
GBV	Gender-based violence
GHI	Global Health Initiative
IUD	Intrauterine device
IAVI	International AIDS Vaccine Initiative
iCCM	Integrated community case management
IMSaT	Intermittent mass screen and test
IRS	Indoor residual spraying
ITN	Insecticide-treated net
IVCC	Innovative Vector Control Consortium
LNG	Levonogestrel
MDR-TB	Multidrug-resistant TB
MERS	Middle East Respiratory Syndrome
MMV	Medicines for Malaria Venture
MTB/RIF	<i>Mycobacterium tuberculosis</i> /rifampicin
MVDP	Malaria Vaccine Development Program
NGO	Non-governmental organization
NIH	National Institutes of Health
PCV	Pneumococcal conjugate vaccine
PEER	Partnerships for Enhanced Engagement in Research
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PMTCT	Prevention of mother-to-child transmission of HIV
PrEP	Pre-exposure prophylaxis
PRISM	Performance of Routine Information Management
PROVE IT	Policy Relevant Outcomes from Validating Evidence on Impact
R&D	Research and development
RDNS	Rang-Din Nutrition Study
R2P	Research to Prevention project
STREAM	Standardized Treatment Regimen of Anti-Tuberculosis Drugs for Patients with MDR-TB
TB	Tuberculosis
TFV	Tenofovir
UBT	Uterine balloon tamponade
UNCoLSC	UN Commission on Life-Saving Commodities
USAID	U.S. Agency for International Development
WHO	World Health Organization



# EXECUTIVE SUMMARY

At the founding of the U.S. Agency for International Development (USAID), President John F. Kennedy said, “Our problems are man-made, thus they can be solved by man.” For more than 50 years, USAID has leveraged science, technology, and research to develop, introduce, and deliver low cost, high-impact interventions improving health and saving lives. This longstanding commitment has resulted in the development of technologies, tools, and interventions like oral rehydration salts to prevent diarrheal deaths in children and the Demographic and Health Surveys – the standard for demographic and health information for measurement and decision-making.

President Barack Obama has committed his administration to ending extreme poverty in two decades. In support of this objective, USAID is undertaking the Global Health Initiative (GHI) to accelerate the rate of progress in reducing preventable mortality and improving health. GHI is implemented through three focus efforts that target the main causes of mortality and burden of disease in developing countries: Ending Preventable Child and Maternal Deaths, Creating an AIDS-Free Generation, and Protecting Communities from Infectious Diseases. Each one has ambitious but achievable targets and includes a strong focus on measurement and the development and application of research and innovation.

In support of these goals, USAID has renewed its commitment to innovation and health systems strengthening through efforts such as the Grand Challenges initiatives, which include the Saving Lives at Birth and Fighting Ebola programs, as well as through the establishment of the Office of Health Systems.

In partnerships with developing countries, USAID is well positioned to scale up evidence-based interventions. To accelerate the development and introduction of research, USAID works along a research-to-use continuum. Its approach involves needs assessments to inform research, product development, and other activities that are needed to guide and accelerate the introduction and scale-up of evidence-based interventions. Under this research-to-use strategic framework, we are better able to identify and accelerate the availability of the

most promising opportunities that would benefit partner country health systems.

USAID also engages with multiple supporting partners, including the U.S. Centers for Disease Control and Prevention, the National Institutes of Health, the Department of Defense, multilateral and donor agencies, foundations, universities, non-governmental organizations, and commercial-sector partners, to address country-specific and global challenges, and establish the evidence base for the development of consensus on technical and policy issues. Concurrent to its research and research introduction efforts, USAID strengthens research and technical capabilities in partner countries.

This current report is a progress update on the health research goals, established as part of the Bureau for Global Health’s 5-year (2011–2015) Health Research Strategy. USAID uses a managed research process to meet these goals. Most objectives are in the final stages or have already been completed. Highlights of this year’s report include the following accomplishments:

## **Ending Preventable Child and Maternal Deaths**

- Advanced, in partnership with the Helping Babies Breathe program, the introduction and coverage of life-saving newborn resuscitation training and devices in health facilities in seven countries. USAID is developing a low-cost and easy-to-use upright neonatal resuscitator. This model has the potential to save more lives because it delivers more volume, prevents air leakage, and has easier assembly and disassembly.
- Supported three promising new insecticide candidates to fight malaria that are anticipated to reach the final stages of development in 2019. These new insecticides will be particularly important for addressing resistance in areas that are highly endemic to malaria.
- Chlorhexidine, a low-cost antiseptic, has been demonstrated to reduce neonatal mortality from umbilical cord infection. USAID funded early clinical trials, accelerated its development, supported the scale-up in Nepal through Saving Lives at Birth, and is now accelerating its introduction in 12 more countries.

- Testing strategies to successfully introduce new products to increase options for women-initiated contraception. These innovative methods were designed to address women’s concerns about side effects, options for infrequent sex, and safety during breast feeding.
- Anticipated challenges to adoption of effective cookstove technologies to help reduce indoor air pollution. These USAID-funded studies have contributed to the understanding of cooking behaviors and the most effective ways to maximize low emission cookstove use.

## **AIDS-Free Generation**

- Continued to support promising, large-scale, efficacy trials in HIV prevention. Ongoing studies include examining tenofovir vaginal gel and the monthly dapivirine vaginal ring. USAID is undertaking planning for licensure, introduction, and scale of new HIV prevention products for women.

## **Protecting Communities from Infectious Diseases/Global Health Security Agenda**

- Advanced development of diagnostic tools and regimens to address tuberculosis (TB). USAID supported tool diagnostic development to more effectively detect TB in individuals with and without HIV and supported research to examine regimens that improve the treatment of multidrug-resistant TB (MDR-TB).
- Identified novel viruses to more effectively target surveillance, raise awareness of risks, and engage partner governments on issues of early response. USAID supported a new set of viral pathogen detection protocols and a global network of laboratories to obtain information on 315 novel viruses.

America’s investments in global health research and development not only improve and save lives, but also help build stronger families, communities, and nations; foster stability; and contribute to economic growth. Though global health research and development represents a small portion of the federal budget, it makes important contributions toward advancing our national security, promoting our economic interests, and reaffirming our country’s exceptional role in the world.



# ENDING PREVENTABLE CHILD AND MATERNAL DEATHS

USAID makes evidence-based investments to help protect the health and well-being of newborns, toddlers, children, pregnant women, and their communities. Whether it's helping to provide proper nutrition, delivering life-saving vaccines, protecting newborns from infection, treating diarrhea, pneumonia and malaria, providing options for family planning and reproductive health, or providing medicines to prevent maternal death, USAID remains a leader in the global effort to end preventable child and maternal deaths (EPCMD). As part of the research agenda for EPCMD, USAID leverages multi-stakeholder partnerships with both the public and private sectors to drive evidence-based solutions.

One example of our research strength can be seen through our work in the commodities sector. Research partnerships with the UN Commission on Life-Saving Commodities (UNCoLSC) help support greater uptake of 13 life-saving commodities for maternal and child health. Work on injectable antibiotics, chlorhexidine and neonatal resuscitation for newborn health, address two of the leading causes of preventable newborn deaths – sepsis and asphyxia. Collaborative UNCoLSC teams that work on misoprostol, oxytocin, and magnesium sulfate have made great strides toward influencing maternal health policies and reducing barriers to access. USAID's long-standing investment in oral rehydration solutions and zinc to support child health built the evidence base that led to a WHO and UNI-

CEF signed agreement to revise diarrhea treatment protocols. Reproductive health commodities, such as female condoms, implants, and intrauterine devices (IUDs), are also part of a research portfolio that support innovative technologies that give women choices for healthy timing and spacing of births.

Our research strength is also apparent through our global coordination efforts. Together with UNICEF and WHO, seminal research studies, such as those examining simplified antibiotic regimens to treat newborn sepsis and chlorhexidine antiseptic for newborn cord care, are influencing global practices and guidelines for the treatment of infections. USAID-supported discoveries in nutrition, such as the finding that a two cents dose of bi-annually administered vitamin A can reduce child mortality by 34 percent, continue to have a global impact. Research conducted through initiatives, like Helping Babies Breathe, are helping to ensure that birth attendants recognize and learn the resuscitative techniques that can substantially reduce newborn deaths from asphyxia. In addition, USAID-supported research studies have led to a 72 percent drop in childhood deaths from pneumonia and diarrhea, wide-scale production and availability of fortified sugar, oils, and flours to increase nutrients, and significant decreases in maternal mortality ratios.

Research is integral to accelerate our efforts and achieve our goal to end preventable child and maternal deaths. This section of the report will go into greater detail to highlight USAID's most recent research investments in the top threats to child and maternal survival.

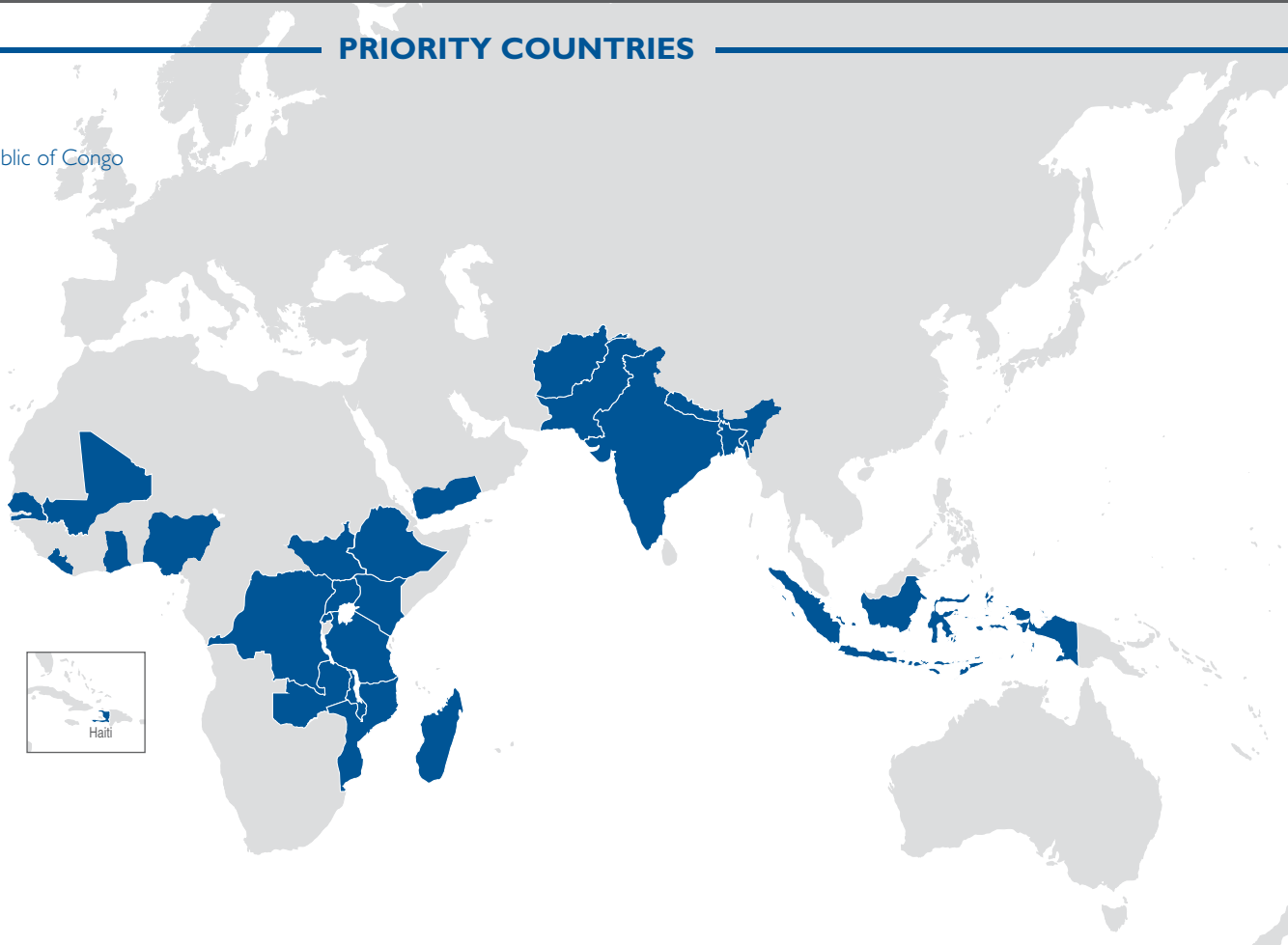


# MATERNAL AND NEWBORN HEALTH

*The loss of a mother's life is a tragedy. When a mother dies as a result of pregnancy or childbirth, it threatens her newborn's chance of survival, lowers her other children's chances for survival and education, and hurts her family and her country's prosperity. Despite recent advances, 289,000 women still die every year during pregnancy or childbirth, and 2.9 million babies die within the first month of life.*

## PRIORITY COUNTRIES

- Afghanistan
- Bangladesh
- Democratic Republic of Congo
- Ethiopia
- Ghana
- Haiti
- India
- Indonesia
- Kenya
- Liberia
- Madagascar
- Malawi
- Mali
- Mozambique
- Nepal
- Nigeria
- Pakistan
- Rwanda
- Senegal
- South Sudan
- Tanzania
- Uganda
- Yemen
- Zambia



## USAID RESEARCH INVESTMENTS IN

USAID and NIH convene a newborn infection prevention meeting where experts identify chlorhexidine (CHX) as an inexpensive and simple intervention to reduce a major cause of child mortality.

2005

Nepal study shows that applying CHX to umbilical cord stump lowers rate of severe infection by 75% and reduces neonatal mortality by 34%.

2006

2007

USAID and PATH submit CHX to WHO Model List of Essential Medicines.

2008



2009

### USAID Concurrent R&D Investments

Companion studies – Pakistan and Bangladesh  
 Feasibility research – Nepal and Bangladesh  
 Product development – Global effort

## HEALTH RESEARCH GOALS

To reduce the leading causes of maternal and neonatal mortality, we are committed to:

- **Develop and introduce evidence-based interventions for care during pregnancy and at birth.**
- **Strengthen and standardize obstetric care for the prevention, management, and treatment of fistula.**
- **Design, evaluate, and introduce evidence-based interventions to reduce newborn morbidity and mortality from birth asphyxia.**
- **Develop, test, and introduce community-based health interventions to treat and prevent newborn infections.**
- **Develop scalable approaches for integrating maternal, family planning, and neonatal health services.**
- **Assess evidence-based approaches to improve the access and utilization of quality maternal, neonatal, and child health interventions.**
- **Develop standardized criteria and effective tools for measuring maternal and perinatal mortality and morbidity.**

## BACKGROUND

While great strides have been made to reduce maternal mortality in the lead-up to reaching the Millennium Development Goal target year of 2015, 289,000 women are still dying every year during or around pregnancy and childbirth. The vast majority of these deaths (99 percent) occur in low-income countries, primarily in sub-Saharan Africa and Asia. Moreover, while neonatal mortality has decreased, 2.9 million babies still die within the first month of life. Reductions in maternal and newborn mortality have been slower than those in other health areas.

The main causes of maternal death – hemorrhage, pre-eclampsia and eclampsia, sepsis, and unsafe abortion – are all largely preventable. Similarly, babies are also dying of mainly preventable causes, including sepsis, asphyxia, and preterm birth.

High quality, targeted research that can lead to the design and scale-up of life-saving interventions can help “bend the curve” of maternal and newborn death and disability. USAID’s research is an integral part of ending preventable child and maternal deaths. This research aims to influence policy and practice and addresses entry points for action from the household and community level to the various echelons of service delivery. The research in maternal and newborn health takes a partnership approach, bringing together public and private sectors, academic institutions, implementing agencies, and other bilateral and multilateral development partners.

USAID is also at the forefront of building and promoting the critical area of implementation research and delivery science to be able to specifically address bottlenecks to scale-up and use continuous quality improvement and learning to achieve more rapid results in averting death and disability.

## 1. Improving Maternal Care Interventions

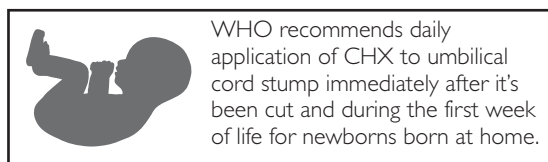
### *Respectful Maternity Care*

Disrespect and abuse in maternity care is acknowledged to be widely practiced across developing countries and is cited as one of the primary reasons for low facility delivery rates. However, little evidence exists to establish the actual prevalence of this problem. USAID is supporting implementation research to assess the drivers of, and measure the prevalence of, disrespect and abuse in western Kenya. This research aims to inform the design of interventions to reduce disrespect and abuse. The study’s findings showed that 20 percent of women reported feelings of humiliation while receiving maternity services, and 90 percent of physicians reported having witnessed disrespect and abuse. These findings are feeding into a large-scale advocacy campaign led by the White Ribbon Alliance and supported by USAID to make clients, providers, and governments aware of the problem and effect policy change to facilitate a reduction in disrespect and abuse. This has led to a global consultation convened by WHO.

### *Quality of care*

USAID funded research to study the quality of care of maternal and newborn health-

## CHLORHEXIDINE FOR NEWBORN CORD CARE



2010

2011

2012

2013

2014



Through support from Saving Lives at Birth, the Nepal Ministry of Health and Population add CHX to national program.

USAID is rolling out CHX in 12 of our priority countries, which could result in saving 160,800 newborn lives by 2019.

care services. Among strengths identified in maternal care, the vast majority of providers (across 52 facilities in Tanzania) used partographs to track the progression of labor and checked for lacerations during the third stage of labor. Areas for improvement included handwashing and correct use of uterotonics for prevention of postpartum hemorrhage.

In newborn care, the study found the appropriate, proper, recommended practice of cutting of the cord with a clean blade and cleaning and wrapping of the baby immediately after birth to be nearly universal. However, skin-to-skin care and immediate initiation of breastfeeding were found to be lacking in most facilities. The data collected will provide the baseline for a quality improvement intervention project.

In addition, a USAID-supported initiative carried out a household survey of recently delivered women in Ethiopia, which highlighted relatively small differences in newborn care practices between babies delivered at home and in facilities. Positive practices included exclusive breastfeeding in 87.6 percent of recently delivered women and wrapping of the baby before delivery of the placenta in 82.3 percent of women. Harmful behaviors, including discarding of colostrum, were committed by almost half of recently delivered women, and bathing the baby within the first day of life was done in 74.7 percent of cases. This important USAID-funded study points to the need for a multipronged approach to improving newborn quality of care through a number of different actors and approaches in the healthcare system and in the community.

#### **Commodities support**

USAID has been actively supporting the work of the U.N. Commission on Life Saving Commodities to ensure that

essential medicines, products, and services are available in countries that need them to reduce morbidity and mortality in mothers, newborns, and children under five. Specifically, USAID has led the Commission's efforts in securing supplies of high quality injectable antibiotics for presumed sepsis in infants; neonatal resuscitators to address birth asphyxia; misoprostol and oxytocin for the prevention and treatment of postpartum hemorrhage; and magnesium sulfate for the treatment of pre-eclampsia and eclampsia, among other commodities.

#### **2. Managing Fistula Care**

Obstetric fistula is a condition in which an abnormal opening or fistula forms between the rectum and the vagina or between the urinary tract and the vagina. This maternal complication can be the result of prolonged, obstructed labor. It is particularly likely to occur when appropriate emergency obstetric care is not available – and it may lead to severe lifelong disabilities.

USAID, in partnership with WHO, completed an eight-country study in Africa comparing the efficacy and safety of 7-day catheterization with 14-day catheterization following fistula repair surgery. The shorter catheterization was found to be safe and effective and can reduce hospital stays, lower cost per repair, and increase capacity for treating fistula patients. In Guinea, a study of community-level fistula prevention highlighted the importance of community-level attention and facility-level counseling on birth preparedness among pregnant women as an effective means to increase delivery at a health facility.

#### **3. Treating Birth Asphyxia**

The Agency has also been a primary partner of the Helping Babies Breathe

initiative to educate trained birth attendants to resuscitate newborns suffering from asphyxia. The newest technological advancement in this field is the upright resuscitator, which has been bench-tested for eventual field trials. This new device promises to be easier to use and less expensive to produce, thereby facilitating uptake of this key commodity to help neonates with difficulty breathing at birth to survive.

#### **4. Preventing and Treating Newborn Infections**

##### ***Chlorhexidine for umbilical cord care***

USAID is engaged in implementation research in support of the use of chlorhexidine for cord care to reduce neonatal sepsis, a leading cause of newborn death. Chlorhexidine is an antiseptic that when applied to a newly cut umbilical cord can reduce mortality by 24 percent. These efforts have resulted in the new WHO-issued guidelines recommending the daily application of 7.1 percent chlorhexidine to the cord stump for the first week of life in high neonatal mortality settings. These new guidelines set the foundation to introduce and scale up use of chlorhexidine in 12



developing countries – with more slated to come on-stream in the coming year.

### **Simplified antibiotic treatment of young infants**

Severe infection is one of the primary causes of death in newborns in lower income countries. Poor families face a myriad of issues when attempting to access the recommended standard of 7–10 antibiotic injections. USAID has supported research to test the efficacy of delivering treatment for sepsis through a short-course combination of injectable and oral antibiotics in home-based settings in Bangladesh. Community-based trials are also ongoing in Pakistan, Democratic Republic of Congo, Kenya, and Nigeria and hold promise for delivering life-saving care against sepsis in newborns and young infants.

## **5. Integration of Services**

Integration of service delivery between overlapping and/or complementary sectors of healthcare has been promoted as a promising way to reach more of the target populations. Results from the Healthy Fertility Study in Bangladesh, which assessed the feasibility and impact of integrating postpartum family planning with a maternal, newborn, and child healthcare package, are expected this year. Similarly, the Morogoro Evaluation Program in Tanzania provided evaluation support to Ministry of Health and Social Welfare to increase the coverage, quality, and continuity of integrated maternal, newborn and child health/HIV and AIDS services.

## **6. Access and Utilization of Care**

### **Financial incentives for maternal care**

USAID and the National Institutes of Health convened an evidence summit in 2012 to review impact of financial incentives on both the demand and supply side, on the quality and utilization of maternal healthcare, and on health outcomes. The results from that summit have recently been published in a peer-reviewed journal. Overall, the evidence points to the success of various forms of financial incentives – especially conditional cash transfers – in improving health service utilization. Other evidence revealed a somewhat mixed experience as to the effects on quality of care in financial incentive schemes and inadequate data on the impact on health outcomes.

One particular area of interest for USAID under financial incentives is results-based financing, which is rapidly becoming a key platform for health systems reform. Results

based financing programs are premised on the notion that payments should be made for outputs instead of inputs and that these payments, or incentives, can spur efficiency, motivate staff to perform better, and improve quality of care. USAID has funded an evaluation of the impact of performance-based incentives – a variant of results-based financing – on maternal and newborn health indicators in Malawi. The baseline for this study has been completed and shows an overall low level of quality of maternal and newborn healthcare in the facilities that will participate in the performance-based incentives program, even if the rate of institutional delivery is high in Malawi (over 70 percent). The study should shed light on the effects of incentivizing improved quality of care.

### **Task-shifting**

In low-resource settings, task-shifting to train lower-skilled healthcare workers (e.g., non-specialists) to perform cesarean sections is now seen as a crucial health systems intervention to expand access to emergency obstetric services. USAID is supporting research in Kenya, Malawi, and Zambia to document the process of implementing task-shifting in order to expand the human resource base available for life-saving emergency obstetric care. These studies should inform in-country stakeholders as well as a wider group of countries undertaking task-shifting with respect to improvements in program roll-out and institutionalization.

### **Equity**

A central area of focus for USAID is achieving an equitable distribution of and access to healthcare services. Although many poor or disadvantaged women do not access maternity services, the causes are not fully understood. Through a USAID-funded project, in-country partners in Guatemala, Kenya, Tanzania, and Indonesia are conducting field implementation research studies to examine the reasons for inequitable access and utilization of maternal and neonatal healthcare services. These studies are addressing both the household and community-level factors as well as evaluating the effect of evidence-based budgeting in increasing equity in maternal and newborn healthcare.

### **Quality of care**

Quality of healthcare is an area in which USAID expects to continue its intensive engagement, given the potential to reduce preventable deaths with improved healthcare practices. To this end, USAID-

supported research around quality of care has greatly influenced WHO's decision to endorse the use of a uterotonic during the third stage of labor as well as the monitoring of this usage. USAID research to support measurement has further helped develop a precise definition of the indicator for assessing prophylactic use of a uterotonic to prevent postpartum hemorrhage.

To promote quality of care in maternal and newborn health within the context of health systems strengthening, a USAID project has piloted a study of the use of routine service data to promote continuous quality improvement in Eastern Province of Kenya. This initiative is also intended to inform improvements in the Health Information Management System nationally.

## **7. Measurement Tools**

### **Collaborative work**

WHO published new analyses of the USAID-supported WHO Multi-Country Survey on Maternal and Newborn Health. It covers a wide range of issues, including the major causes of maternal mortality and severe morbidity and social determinants of health. These results are presented in a special supplement of 12 papers, an editorial and a commentary. These are data from more than 300,000 births in 29 countries and a rich source of information and new analyses, such as on the significant proportion (21 percent) of maternal deaths that occur due to indirect causes; the strong association of low maternal education with severe maternal complications; the necessity of providing quality intrapartum care to prevent perinatal death in women with complications; and the need to discourage provider-initiated pre-term delivery.

### **Research to policy**

USAID-supported research initiatives have influenced global health policy in maternal and newborn health and have led to critical changes in guidelines. Without this support, the cascade of necessary policy and strategy changes in low- and middle-income countries would not be engendered. Validation research around measurement through a maternal and child health implementation project has pointed to the need to include two new indicators within the currently used inventory: "newborn placed skin-to-skin on mother's chest" and "companion present during labor or birth." Indicators are essential to measuring progress in our efforts to reduce preventable death and disability.

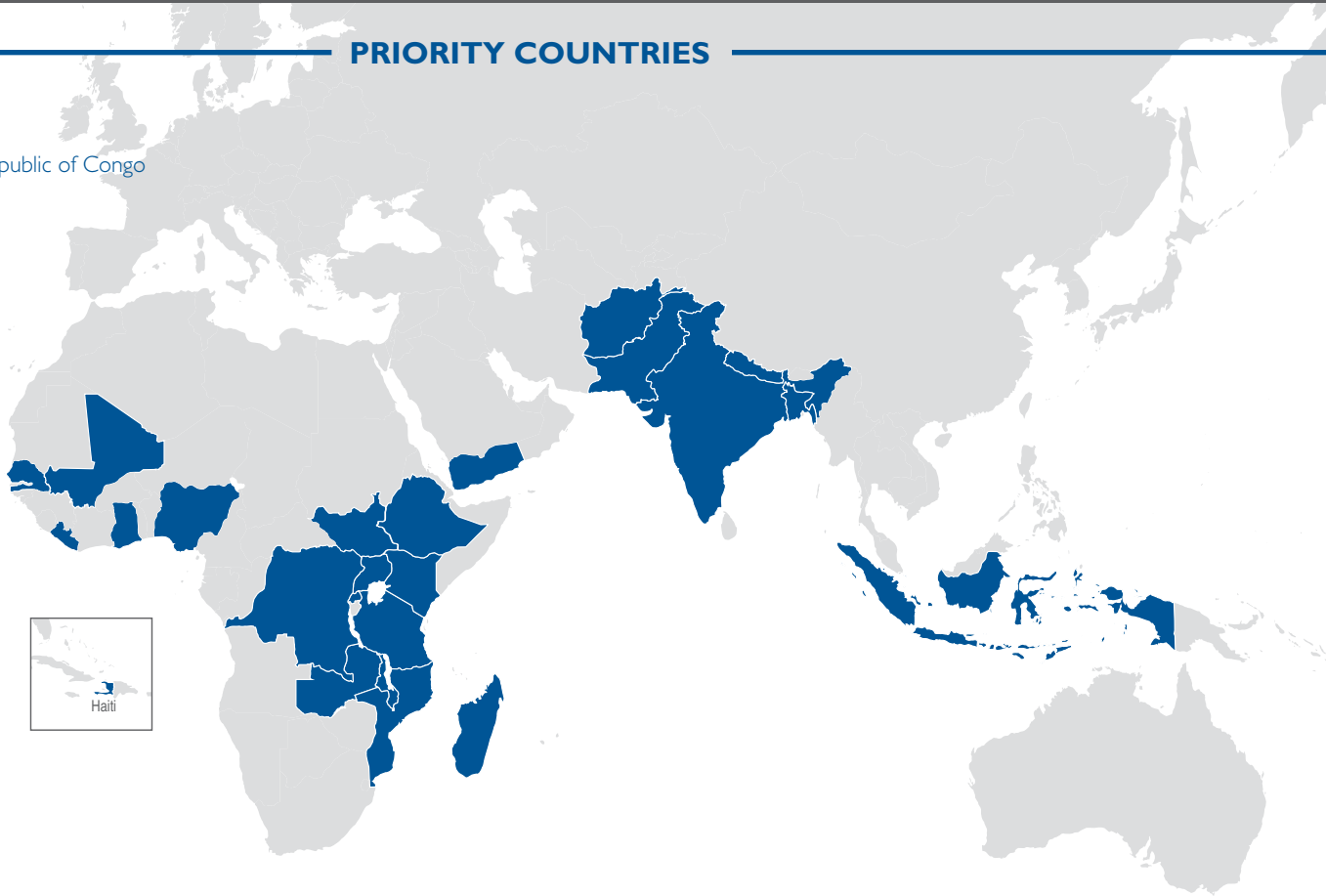


# CHILD HEALTH

While child mortality rates have decreased by 49 percent between 1990 and 2013, there are still more than 6.3 million children who die before their fifth birthday every year. Most of them will die from an illness that is completely preventable. Investments in evidence-based approaches like integrated community case management, are needed to help ensure that every child has access to life-saving treatments and services in their community.

## PRIORITY COUNTRIES

- Afghanistan
- Bangladesh
- Democratic Republic of Congo
- Ethiopia
- Ghana
- Haiti
- India
- Indonesia
- Kenya
- Liberia
- Madagascar
- Malawi
- Mali
- Mozambique
- Nepal
- Nigeria
- Pakistan
- Rwanda
- Senegal
- South Sudan
- Tanzania
- Uganda
- Yemen
- Zambia



## USAID RESEARCH INVESTMENTS IN INTEGRATED COMMUNITY

WHO/UNICEF launches integrated management of childhood illness to address the five major causes of child mortality – diarrhea, pneumonia, malaria, measles, and malnutrition.



1992 •••• 2000 2001 2002 2003 2004 2005 2006

Integrated Community Case Management (iCCM) was established to include family and community health practices.





## HEALTH RESEARCH GOALS

To reduce the leading cause of mortality in children aged 0–5, we are committed to:

- **Support implementation research to inform the uptake of integrated community case management.**
- **Develop and test cost effective approaches to decrease the incidence of acute lower respiratory infections due to household air pollution.**
- **Evaluate interventions to increase the use of efficacious diarrhea treatments.**
- **Develop and test scalable approaches to improve drinking water quality and access, use of sanitation, and hygiene behaviors.**

## BACKGROUND

While the world has witnessed a marked decline in child mortality over the past 50 years, there are still 6.3 million children who die before the age of 5 each year. Most of these deaths occur in developing countries. Many are preventable. In 2012, the Child Survival: Call to Action was convened by USAID and the governments of Ethiopia and India in collaboration with UNICEF, to show a global commitment to reducing

child mortality. Through A Promise Renewed, USAID is working to end preventable child and maternal deaths by strengthening global partnerships and scaling up effective and affordable tools that positively impact the lives of children.

In June of 2014, USAID again worked with the governments of Ethiopia and India in collaboration with UNICEF and the Bill & Melinda Gates Foundation to take stock of progress and discuss challenges to end preventable child and maternal deaths. USAID continues to support research to accelerate progress and reach this goal. Predictive models support the idea that ending preventable child deaths in a generation is achievable but only if the rate of reduction is increased, and progress is accelerated.

USAID aims to positively impact the lives of children in vulnerable communities by rapidly accelerating this decline in child mortality. To meet this challenge, the Bureau for Global Health prioritizes its child health efforts in 24 low- and middle-income countries in Africa, Asia, and the Caribbean. Evidence from around the globe has demonstrated that through concerted global action, sound strategies, and committed leadership, significant reductions in child mortality are achievable in low- and middle-income countries.

### I. Integrated Community Case Management

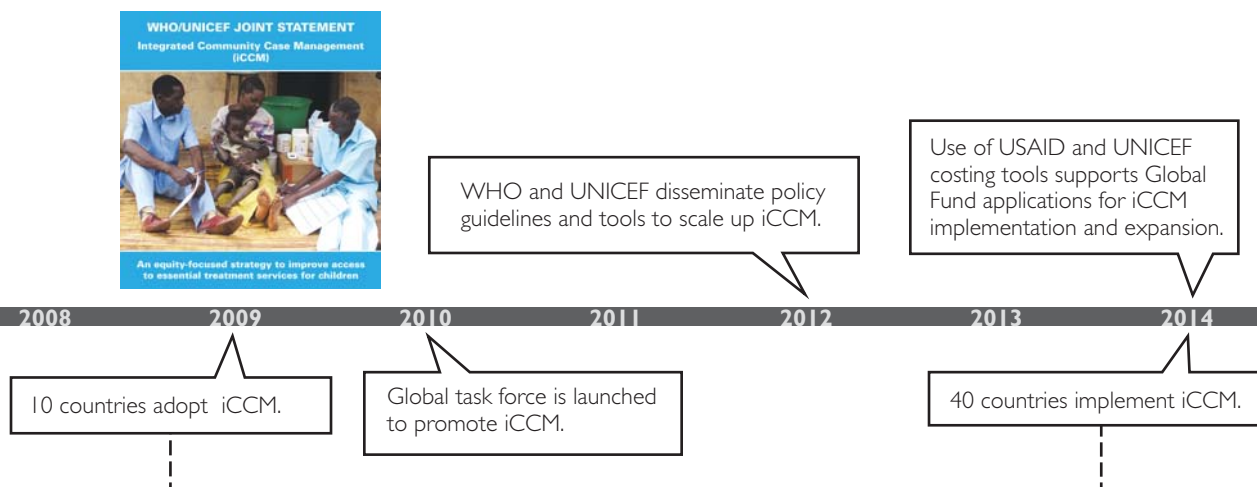
To address the treatment of devastating childhood illnesses like pneumonia, diarrhea, and malaria that continue to be among the

leading causes of mortality for children under 5, USAID funds research on innovative, community-based interventions for equitable delivery of quality products and services. Integrated community case management (iCCM) is an intervention strategy that extends the case management of childhood illness beyond health facilities. This approach enables families who do not have access to health facilities to receive life-saving treatments for the children in their communities.

USAID is committed to funding iCCM research and educational events that will help enhance learning opportunities across countries and partners. In March 2014, USAID supported the iCCM Evidence Review Symposium in Ghana, which brought together more than 400 individuals from 35 countries in sub-Saharan Africa and also 59 international partner organizations. The aim of the symposium was to review the status of evidence in key iCCM program areas, draw out priorities, share lessons, and address gaps for improving child health. USAID works to assist African countries in taking action on the key iCCM findings that were presented based on eight thematic areas: policy setting and coordination, human resources, quality assurance, supply chain management, costing and financing, monitoring and evaluation, social mobilization, and impact evaluations.

To refine the process of rolling out global technical guidelines at the country level, USAID funded a review to compile training and supervision materials for community health workers across 10 African countries. This study explored the process by which the

## CASE MANAGEMENT TO TREAT CHILDHOOD ILLNESSES



# IMMUNIZATION

USAID supports research to understand the factors leading to good performance of the routine immunization system. Access to services in some regions does not always translate to uptake of quality immunization services. As a result, millions of children remain under-immunized in developing countries.

USAID-funded research has investigated key questions in the field of immunization, such as: Why are children not vaccinated? USAID-supported analyses revealed that the main reasons for under-vaccination were related to access to immunization services, attitudes of health staff, fear of side effects, conflicting priorities, and parental knowledge and beliefs. In addition to those identified barriers, a mixed methods study in Indonesia concluded that low immunization coverage may also be attributed to large family size, lack of support from husbands and paternal grandmothers, and seasonal migration patterns. USAID also funded studies that investigated the impact of vaccine introduction on immunization and health systems of countries. Findings from these studies revealed that the benefits of new vaccine introduction included reduction in disease burden as well as improvements in surveillance, cold chain strengthening, training, and injection safety.

WHO estimates that more than half of annual deaths from pneumococcal disease are among children under 5 years of age, and most are in developing countries. Because clinical trials of pneumococcal conjugate vaccines (PCVs) in infants have shown significant benefits against some of the severe forms of pneumococcal disease, it has been recommended that PCVs be introduced into the immunization schedules in countries with high rates of childhood mortality. In Kenya, PCV introduction and delivery is being co-financed by the Kenyan government and Gavi, The Vaccine Alliance, which is a public private partnership supported by a number of partners including USAID. USAID supports economic research that will assist policymakers in planning for continued vaccine delivery beyond that 10-year co-financing period. Findings from this analysis revealed that the annual cost of delivering PCV10 or PCV13 (vaccines that cover some of the most severe forms of pneumococcal disease), would lead to a 43 percent reduction in pneumococcal disease, which would not only lend itself to cost-savings, but also would ultimately lead to a significant reduction in annual childhood mortality.

countries adapted relevant global technical guidance for use in their individual country contexts. These findings will help the global community understand how best to support countries through adaptable global recommendations.

## Policy

Though the benefits of iCCM are well documented, there is still an urgent need to support policies that will allow for effective programmatic scale-up of these services. As such, USAID supported policy studies to help identify the barriers and facilitators of national- and global-level policy reform for iCCM programming. A study of iCCM policies in six sub-Saharan African countries revealed the need to tailor policies at the country level, so they may better align with health system needs and have a greater likelihood of long-term sustainability.

## Monitoring Approaches

Additional research supported by USAID in Ethiopia, Malawi, Mali, and Mozambique examines the role of episodic monitoring to strengthen implementation and enhance the impact of iCCM on child survival. A series of monitoring and evaluation studies are currently investigating the role of data quality, data collection, and improved documentation systems at the national

and district levels. Early results suggest that the use of cell phones in conjunction with simple assessment approaches is an effective management tool for monitoring worker performance.

## Costing

USAID also supported costing studies to better understand and validate the requirements for expanding iCCM in developing countries. A costing tool is being validated at the country level to help countries choose the best structure of iCCM programs. These tools, which will help inform projections on iCCM budgets and sustainability, are now being applied to help a number of countries, such as Nigeria, leverage additional iCCM resources that are available through the Global Fund to Fight AIDS, Tuberculosis and Malaria's New Funding Model. Initial experiences using this iCCM costing tool have proved promising, and other donors have now started supporting its use in additional countries, such as Burkina Faso.

USAID is particularly interested in supporting research that will inform course corrections to ensure that investments have the maximum benefit possible. When initial quantitative studies from UNICEF suggested that a community health program in Mali

was suffering from lower utilization than was needed to achieve optimal health benefits, USAID funded a qualitative study to identify and further explore the reasons behind this pattern, so that the program could be re-designed in ways that will hopefully address this issue and increase utilization.

## Implementation Science

As implementation experience to date has shown, in order to be sustainable and effective, iCCM programs need to be constructed and rolled out within a pre-existing community health strategy. USAID is currently funding an operational research study in Kenya that aims to document the implementation impact of adding an iCCM technical module onto the existing community health worker platform. When available, these findings will inform the scale-up of iCCM within Kenya, and will maximize efforts to end preventable child deaths by enhancing efforts globally to leverage existing health systems effectively and efficiently.

## 2. Household Air Pollution

In developing countries, indoor air pollution from inefficient stoves that burn wood, crop waste, dung, or coal is responsible for the deaths of more than 4 million people annually. More than 400,000 of these deaths occur among children under 5 years

of age. In addition, inefficient stoves put millions of girls and women at risk for gender based-violence, as they leave the safety of their communities each day in search of firewood. In accord with the Agency's mission to end preventable child and maternal deaths and the Global Alliance for Clean Cookstoves mission to achieve universal adoption of clean cookstoves and fuels, USAID supports the use of low emission cookstoves to help reduce indoor air pollution, help protect girls and women, and lower the risks of acute lower respiratory infections in children.

Because human behavior influences whether new meals, new cooking methods, or new cooking schedules can be accommodated, the adoption of clean cookstoves often requires the adoption of new cooking behaviors. Recently, cookstove manufacturers have begun using the results of behavioral studies to design their new stoves (e.g., adding a phone charger to the stove, adding a second burner to allow for two-pot cooking, accommodating more wood sizes in the combustion chamber, etc.). USAID-funded studies on behavior change communication have contributed to the understanding of cooking behaviors and the most effective ways to maximize low emission cookstove use.

USAID-funded studies, in rural Uganda and India, examined consumer attitudes, social norms, and limited knowledge of low emission cookstoves and found that consumers were most interested in reducing household smoke and creating cleaner, more efficient household cooking regimens. Research conducted in a peri-urban district of Uganda, revealed that clean cookstoves contributed to decreased particulate matter in the home – by half in some households. Consumer preference studies in Bangladesh looked at indoor air pollution outcomes, usage, and perception of new low emission cookstove technologies

introduced into households. These studies revealed that while households chose to use new cookstoves consistently, there was not full displacement of traditional cooking methods.

The policy implications of these studies have contributed to mobilizing country level-support. Recently, Ghana developed new policies to bring liquefied petroleum gas – a clean-burning, portable, sustainable, and efficient fuel – to a greater percentage of the population to allow for clean cooking.

### 3. Diarrhea treatment

Oral rehydration solutions and zinc have been introduced in more than 20 priority countries as a treatment for diarrhea in children. It has proven highly effective at managing acute diarrhea. However, there has been a particular lack of attention to treatment strategies for persistent diarrhea, a diarrheal episode that lasts 14 days or more. USAID and WHO are working together to address this research gap. A mixed-methods study on children who died in Bangladesh, Ethiopia, Ghana, India, Pakistan, Uganda, and Tanzania revealed that

the proportion of children who die from diarrhea, as opposed to other causes, varied across the different regions – ranging from 3–30 percent. The kind of diarrhea that was attributed to death in children aged 1–4 years also varied. Acute watery diarrhea accounted for 31–69 percent of diarrheal deaths, acute bloody diarrhea accounted for 12–28 percent of deaths, and persistent diarrhea accounted for 12–56 percent of deaths. Persistent diarrhea accounted for more than 30 percent of deaths in five of the seven countries. More than 40 percent of children who died from persistent diarrhea were malnourished. Future research efforts are aimed at better understanding the burden and treatment practices for persistent diarrhea.

Because the Agency supports research collaboration and active dialogue between global communities of practice, in April 2014, USAID funded WHO to convene the first global meeting on persistent diarrhea in over 10 years. Some of the key areas identified for follow-up included investigating alternative delivery strategies to ensure equitable access to diarrhea-related commodities, determining the appropriate pathways for management of persistent diarrhea in situations where hospital referral is not feasible, and examining treatment successes and failures that help reduce the risk of death and poor growth associated with persistent diarrhea. USAID is committed to continuing to help facilitate global collaboration and technical guidance among diarrhea researchers and to help evaluate future



GEORGE OBANYI/FHI 360

opportunities for scientific advancement and policy improvements in persistent diarrhea management.

#### **4. Water, Sanitation and Hygiene**

Interventions that ensure safe drinking water, proper handwashing, and correct and consistent use of basic sanitation can reduce diarrhea in children under 5 by 25 to 50 percent. Substantial population growth in urban areas and in urban slums causes health concerns for children under age 5. USAID

research is examining water, sanitation, and hygiene behaviors in high-population cities to better understand the relationships between population density, sanitation, and health outcomes. These studies will also address how varying degrees of access to basic sanitation affect the risk of diarrheal diseases and soil-transmitted helminth infections among children living in high-density, low-income settlements compared to similar access in lower density, low-income areas. Findings will help inform the development of evidence-based recommendations

for future policies and sanitation interventions that will aid the curbing of childhood deaths related to water-borne diseases.



# CHILD SURVIVAL AND HEALTH GRANTS PROGRAM

## OPERATIONS RESEARCH PROVIDES EVIDENCE FOR COMMUNITY HEALTH PARTNERSHIPS TO HELP GOVERNMENTS IMPROVE EQUITABLE ACCESS TO HEALTHCARE

USAID's Child Survival and Health Grants Program (CSHGP) strategic partnership model engages and builds the capacity of civil society with host country governments and the private sector for accelerating reductions in maternal, newborn, and child mortality at the national and global levels in priority countries. In this effort, the CSHGP promotes healthy behaviors, improves the quality and equitability of access to services, and informs national policies and strategies. Through the CSHGP, USAID supports new partnerships among international and local non-governmental organizations (NGOs), universities, and ministries of health to generate evidence about how to solve critical challenges in the implementation and scale-up of high-impact maternal, newborn, and child health interventions. Innovative approaches are tailored to local contexts and are relevant to global implementation challenges, such as how best to integrate services within and across sectors; improve the continuum of care to maximize access and lower costs; ensure equity in access and use of services; and build capacity and strengthen systems for accountability to communities.

### HONDURAS (2009–2013)

#### Greater access to primary care for women and children in Francisco Morazán Sur, Honduras

**The Challenge:** Despite the Government of Honduras' commitment to include all communities, challenges remain in achieving equitable coverage of health services.

**The Innovation:** The project collaborated with rural, low-income communities to initiate health posts staffed by community volunteers including trained traditional birth attendants, growth promotion monitors, and community health volunteers.

**Findings:** At the final survey, child mortality in high burden communities was reduced by 6 percent over 3 years. Most of those who benefited from the health posts were in the lowest socio-economic quintiles. By the end of the project, the child survival rates of communities within these quintiles were higher than those at the department (district) and national levels.

**Policy Relevance:** Results of a costing study conducted on the health posts showed that when families found solutions to a child health problem at the community level, as opposed to a rural health post or hospital, they saved from US\$6.03 to US\$70.24. In addition, the costing study found that the Honduran Government could save resources by strengthening medical attention at the community level.

### BURUNDI (2008–2013)

#### Community participation effectively extended the reach of the health system's community health workers through integration of volunteer-led health education groups (Care Groups).

**The Challenge:** In Burundi, there is a critical need to enhance preventative health and nutrition behaviors and improve uptake of curative services at critical times. Community-based implementation strategies that can help community health workers mobilize the wider community for health improvement and behavior change need to be identified, evaluated, and scaled up.

**The Innovation:** The Care Group approach, which trains women in communities to lead health education sessions for groups of women, has proven to be effective in reducing child malnutrition rates and is currently being employed as a behavior change strategy in more than 20 countries. To determine if this model could help community health workers reach more people in Burundi, the study ran a comparison test. Against 40 key child health and nutrition knowledge and practice indicators, the study compared the effects of two community health worker models: (1) Care Groups organized through the health system and led by ministry of health-supported female volunteer community health workers and (2) an NGO-facilitated Care Group.

**Findings:** In both intervention groups, mothers' knowledge of when to begin complementary feeding showed significant increases from baseline, suggesting that the ministry of health-supported community health workers were similarly effective in training and supervising their Care Groups as the NGO-paid Promoters in the traditional Care Group model. There was no significant difference between the two models in achieving improvements in breastfeeding, handwashing, dietary diversity, or oral rehydration solution use, which suggests they are similarly effective.

**Policy Relevance:** The results were shared with the Ministry of Health and UNICEF and further discussions are underway with the Department of Community Health to consider integrating the Ministry of Health-led model of Care Groups into the health system more widely.



Care Group volunteer conducts a home visit.

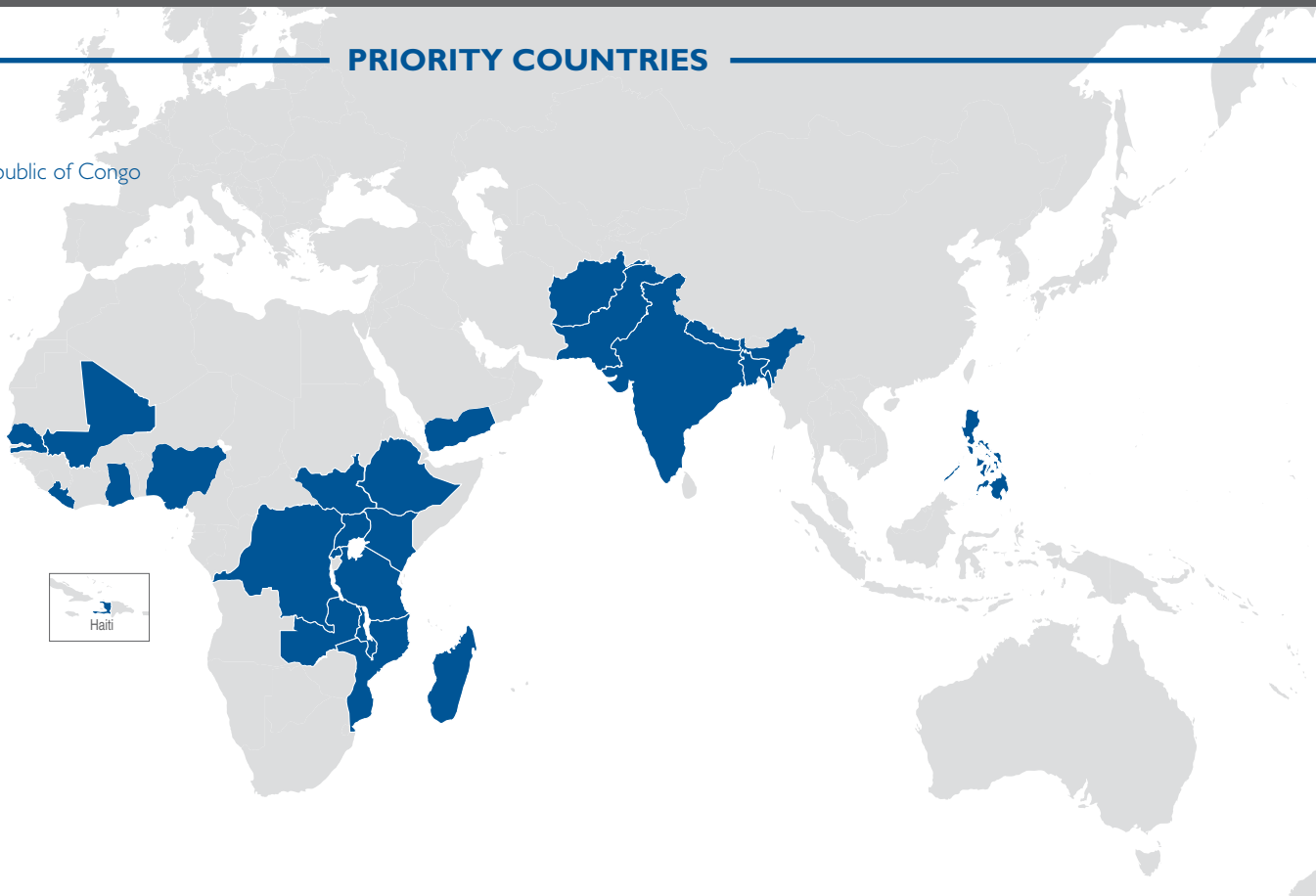
A. FOX/CONCERN WORLDWIDE

# FAMILY PLANNING AND REPRODUCTIVE HEALTH

More than 225 million women in developing countries want to choose the number, timing, and spacing of pregnancies but are not using a modern method of family planning. If unintended pregnancies were prevented, an estimated 5 million under-five deaths and more than 300,000 maternal deaths could be prevented between 2012 and 2020 in the 24 priority countries.

## PRIORITY COUNTRIES

- Afghanistan
- Bangladesh
- Democratic Republic of Congo
- Ethiopia
- Ghana
- Haiti
- India
- Kenya
- Liberia
- Madagascar
- Malawi
- Mali
- Mozambique
- Nepal
- Nigeria
- Philippines
- Pakistan
- Rwanda
- Senegal
- South Sudan
- Tanzania
- Uganda
- Yemen
- Zambia



## USAID RESEARCH INVESTMENTS

USAID studies demonstrated 96% effectiveness of the Standard Days Method®, which is a simple fertility awareness-based method that teaches couples to recognize when they are most fertile.

2002



2007

USAID funds research to introduce and scale up the use of Standard Days Method in five countries.

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## HEALTH RESEARCH GOALS

To improve methods and models for voluntary family planning that benefit women and children, we are committed to:

- Refine, develop, and introduce new contraceptive methods.
- Improve and expand access to family planning methods in developing countries.
- Develop and introduce effective, scalable service delivery models to increase the healthy timing and spacing of pregnancies.

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## BACKGROUND

More than 222 million women in developing countries want to choose the number, timing, and spacing of pregnancies but are not using a modern method of family planning. Factors that contribute to this unmet need include concerns about particular types of contraceptive methods, inadequate or inaccurate information, and poor access to reproductive health services.

USAID advances and supports voluntary family planning programs that enable countries to respond to the needs of their people. Voluntary family planning that is respectful of the rights of individuals to freely choose the timing, spacing, and number of children contributes to the health and well-

being of women and their children. Health benefits result directly from fewer unintended pregnancies, fewer abortions, and longer intervals between births. If all women who want to avoid pregnancy used an effective contraceptive method, approximately 5 million deaths in children under 5 years of age, and more than 300,000 maternal deaths would be averted in USAID's Family Planning and Reproductive Health countries by the end of 2020. If all births are spaced at least 3 years apart, under-5 mortality would fall by 28 percent, and an estimated 1.3 million under-5 deaths would be averted in those priority countries through 2020. In addition to these health-related benefits, a woman's ability to choose the number, timing, and spacing of her children can have improved consequences for her educational attainment, labor force participation, and earnings. These improvements also affect the well-being of her children, household, and community.

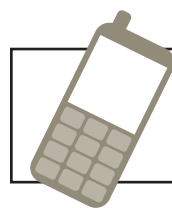
Among women with an unmet need for family planning, many barriers underlie non-use, incorrect use, and discontinued use of contraception. These barriers include concerns about side effects, misperceptions about the risk of pregnancy, opposition from partners or others, and inadequate knowledge about contraception and fertile periods. Limited clinic hours and long distances to service delivery points compound these barriers. In addition, women may find contraceptive methods inconvenient to use, expensive, or inappropriate for their needs.

Research helps to address contraceptive preferences and build family planning and reproductive health programs that are strong, effective, and efficient. USAID supports biomedical research to develop and test novel technologies and methods and implementation research to improve the effectiveness and efficiency of family planning programming, reduce barriers to services, promote method acceptability and continuation, and find new ways to expand services so that they reach underserved women and their families.

## 1. Improving Contraceptive Methods

USAID has been involved in the development of almost every modern contraceptive method in the market today. To combat the barriers to contraception use among women with an unmet need for family planning, USAID continues to invest in biomedical research to: (1) refine existing contraceptive methods to make them more acceptable, affordable, and accessible; and (2) develop new contraceptive methods that better meet the family planning needs of women and their families. Initial work began on the development of a low-cost, safe, and effective biodegradable contraceptive implant that would last for 1 to 2 years, thus reducing a critical gap in the contraceptive method mix between the 3-month injectable and the 5-year implant. Three complementary technologies are being tested, and the most successful will move into the next stages of development.

## IN FERTILITY AWARENESS



USAID-funded research contributed to the development of a mobile phone app for Standard Days Method, called CycleTel, which has been developed, tested, and scaled up in India, and has a target population of 350,000 over the next few years.

2013

Standard Days Method has been introduced in more than 25 countries.

2014



Community health volunteer counsels mother on her family planning options in district of Kita, Mali.

Additionally, preclinical development has continued for two new combination vaginal rings: tenofovir+levonogestrel (TFV+LNG) and dapivirine+levonogestrel (DPV+LNG), both of which are designed to prevent unintended pregnancy and protect against HIV. The TFV+LNG ring began clinical testing in 2014, and the DPV+LNG ring will begin in 2015.

## 2. Improve Approaches to Expanding Access to Family Planning Methods

Implementation research informs the design of culturally appropriate programs and service delivery approaches in order to address gaps in family planning programs, develop tools and materials to improve provider performance, test solutions to overcome barriers to services, and expand successful, evidence-based practices to underserved women and their families. Implementation research supported by USAID tests a variety of innovative models to address social, cultural, and other factors affecting the use of family planning and reproductive health services. One study in India is evaluating a government-run program to prevent child marriage through conditional cash transfers. This involves provision of money to families under the condition they do not marry off their daughters as children. Early marriage leads to early childbearing and high-risk pregnancies. Very young adolescent pregnancy is especially dangerous as girls aged 10–14 are five times more likely to die in pregnancy and childbirth than women in their early 20s.

Preliminary results from this study suggest that girls enrolled in the conditional cash transfer program are more likely to attend school and report higher decision-making power compared to their counterparts who are not enrolled in the program. In 2015, final results on program impact from nearly 10,000 households will be available.

USAID also supports a multi-country study on the effectiveness of community-based approaches to prevent child marriage in sub-Saharan Africa. Baseline results highlight persistent regional child marriage practices such as marriages decided by parents and bride price. Final results in 2015 will provide data on the cost-effectiveness of interventions to prevent early marriage in high-prevalence regions of Burkina Faso, Ethiopia, and Tanzania.

Implementation research also helps develop, implement, and evaluate the effectiveness of interventions that can be scaled up within a particular country. Data are collected on costs to inform replication and scale-up. In northern Uganda, the results of formative research were used to develop a package of interventions to promote gender-equitable attitudes and behavior among adolescents and within their families and communities. The intervention is being tested to determine its impact on reducing gender-based violence and improving sexual and reproductive health outcomes among adolescents and young fathers in post-conflict settings.

USAID has supported research on fertility awareness-based methods from develop-

ment to introduction and scale-up. Previous USAID-supported studies demonstrated the effectiveness of the Standard Days Method® within family planning programs (96 percent effective). The Standard Days Method is a simple fertility awareness-based method that teaches couples to recognize when they are most fertile and informs them on how to avoid unprotected sex during these periods. A USAID-supported assessment of current Standard Days Method programs showed that the method can be taught effectively at all levels of the health system, through community workers and non-health workers, including agricultural cooperative members, and through novel distance-learning approaches. To date, the Agency has funded research to introduce and/or scale up the Standard Days Method in more than 25 countries through both family planning/reproductive health, and maternal and child health services, in both the public and private sectors. Scale-up has occurred in Rwanda, the Democratic Republic of the Congo, Kenya, Mali, Guatemala, and India. Because the Standard Days Method was also shown to improve couple communication, bring new users into the health system, and increase overall contraceptive prevalence, USAID is currently funding research to test strategies to increase fertility awareness and expand access to fertility awareness based-methods at the community level. USAID-funded research also contributed to the development of a mobile phone-based application for the Standard Days Method, called CycleTel. CycleTel has been developed, tested, and scaled up in India. The use of mobile technology for the Standard Days Method has helped make accurate family planning and reproductive health information more widely available and accessible.

In Benin, one study is addressing barriers to low uptake of family planning (9 percent) and factors contributing to high unmet need for family planning (33 percent). Baseline research revealed the importance of social barriers to family planning use, with 36 percent of women reporting that talking about family planning in public was unacceptable. The study is now looking at the effects of an innovative social network approach that is designed to foster a social environment that allows women, men, and couples to exercise their desire to space or limit births through reflective discussion and information sharing within the community. Main results from this study are expected in 2015.



# EXPANDING EFFECTIVE CONTRACEPTIVE OPTIONS

A new USAID project tests strategies to successfully introduce new woman-initiated contraceptive options in pilot countries. These new contraceptives were designed to address various method-related concerns expressed by women as reasons they do not use contraception. The new methods include:

- “one-size-fits-most” diaphragm
- new contraceptive gel
- unique, easier to use female condom
- contraceptive vaginal ring that can be used by breastfeeding women

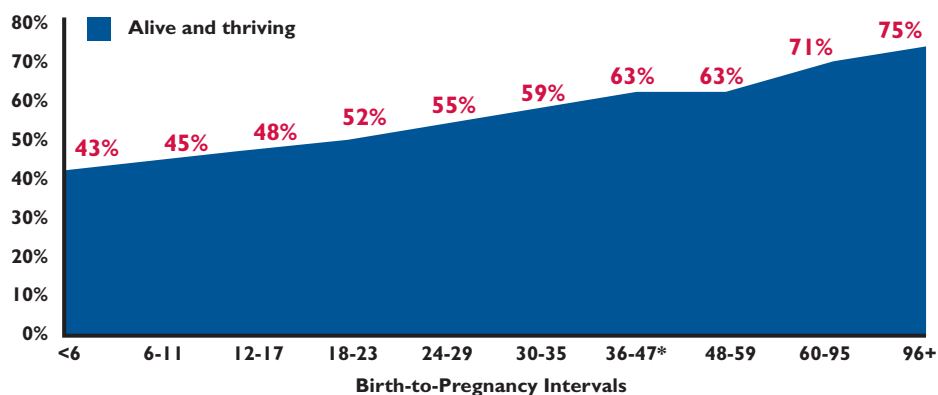
These new methods were designed with significant user input and have the potential to help fulfill the unmet contraceptive needs of millions of women who have concerns about the side effects of other methods, have infrequent sex, or would like more direct control of their contraceptive options. These methods can help women address barriers such as partner opposition through use of women-initiated methods that can be used discreetly. This project uses a product-agnostic approach that can be replicated for additional products and inform the introduction of new family planning methods around the world.

USAID’s Office of Population and Reproductive Health, together with the United Nations Population Fund, the International Planned Parenthood Federation, and WHO, lead an effort to support evidence-based programming for family planning. These organizations jointly facilitate a process for reviewing research from family planning programs in developing countries to identify key practices, that when implemented at scale, are likely to contribute to significant improvements in family planning and reproductive health. These High Impact Practices in Family Planning involve 25 organizations in collecting, synthesizing, and sharing information/evidence on what works in family planning programming. Since 2012, the partnership has published 10 evidence briefs in multiple languages, developed an online interactive map to facilitate south-to-south sharing, and identified key knowledge gaps to inform future research investments.

### 3. Develop Better Models for Healthy Timing and Spacing of Pregnancies

As USAID-supported studies have shown, when pregnancies are timed and spaced to occur at the healthiest times of a woman’s life – between ages 18 and 34 with about 3 years between births – the mother and child are more likely to survive and stay healthy. A 2014 USAID-funded analysis reviewed 45 USAID-funded Demographic and Health Surveys (from 2006 to 2012) that had collected data on more than 1 million births. The analysis found that under-5 mor-

**Figure 1: Percentage of Children Alive and Thriving by Duration of Preceding Birth-to-Conception Intervals**



This figure illustrates the percent of children alive and thriving (not undernourished) by birth-to-pregnancy intervals, shown in months. The longer the birth-to-pregnancy intervals, the greater the percentage of children who are alive and not undernourished. The 36-47 month serves as the reference group for this analysis.

Web source of graphic: <http://dhsprogram.com/pubs/pdf/WP41/WP41.pdf>.

Source: Rutstein, 2008  
\*Ref Group

tality fell by one-third among women who had their children between the ages of 18 and 39, waited 36 months before conceiving again, and had no more than three children. Longer birth intervals were also linked with reduced odds in children of stunting and of being underweight, and also increased the odds of surviving and thriving. Ongoing USAID-funded research is analyzing the impact of birth spacing on neurocognitive development of children.

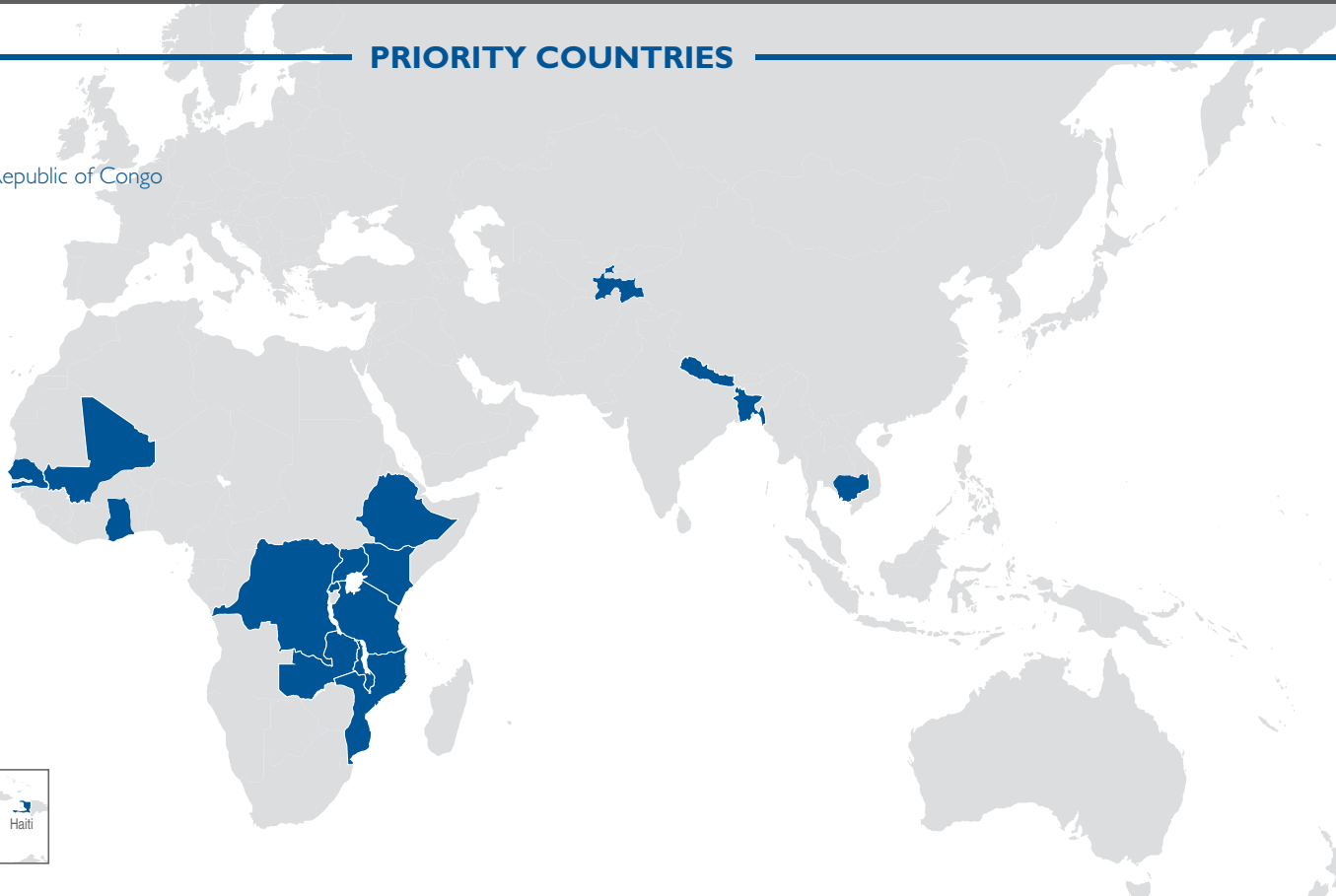
USAID supported a 2013 analysis of interventions designed to help women achieve improved timing and spacing of pregnancy. This review showed that programs that were holistic, multi-disciplinary, and goal-oriented were more likely to reduce teen pregnancy and prevent rapid, repeat pregnancy. It also identified approaches that were ineffective; these included a single contact with the client and failure to design a motivational element in the program.

# NUTRITION

*Undernutrition accounts for nearly half of all deaths among children under 5 years of age. As a result of undernutrition, about 162 million children remain stunted, and 51 million children under-5 years of age suffer from wasting, which is a strong predictor of mortality. Childhood undernutrition not only inhibits a child's physical development, but also is linked to cognitive impairments.*

## PRIORITY COUNTRIES

- Bangladesh
- Cambodia
- Democratic Republic of Congo
- Ethiopia
- Ghana
- Guatemala
- Haiti
- Kenya
- Malawi
- Mali
- Mozambique
- Nepal
- Rwanda
- Senegal
- Tajikistan
- Tanzania
- Uganda
- Zambia



## USAID RESEARCH INVESTMENTS IN

The Rang-Din Nutrition Study (RDNS) – combined pre- and postnatal nutrition interventions to cover most of the 1,000 day window between a woman's pregnancy and her child's 2nd birthday.

2005

2006

2007

2008

2009



National data from Bangladesh (2007) indicate that 43% of under-five children are stunted.

WHO expert review panel concluded that programs using food given with iron, either as centrally processed fortified foods or micronutrients powered supplements, may provide better outcomes and fewer deaths, compared to the previous standard care.

## HEALTH RESEARCH GOALS

To reduce nutrition deficiencies and improve health outcomes through nutrition-sensitive and nutrition-specific interventions, we are committed to:

- **Strengthen and expand the evidence base on integrated multisectoral approaches to improve nutrition outcomes, including stunting and maternal and child anemia.**
- **Support implementation research for improved diet diversity and quality.**
- **Develop, refine, and expand use of state-of-the-art measurement tools for nutrition programs and policies.**

## BACKGROUND

Inadequate nutrition, especially in the critical “thousand day window” from pregnancy to a child’s second birthday, contributes substantially to avoidable deaths and can hamper a person’s physical and cognitive development. At the population level, this undermines countries’ prospects for economic growth. Almost half of pregnant women in the developing world are anemic, which is a key factor in more than 25 percent of maternal deaths and in low birthweight infants. Anemia is caused by deficiencies in several nutrients, such as iron, vitamin B12, folate, vitamin A, occasionally

vitamin B2, and protein-energy malnutrition. Iodine deficiencies as well as iron deficiency-related anemia have been linked to permanent mental retardation when they occur during the fetal period and the first 2 years of life. Nearly 2 billion people suffer from one or more micronutrient deficiencies.

Child stunting, or shortness for age, is a manifestation of deficiencies in many nutrients, including protein and energy, as well as those of micronutrients like vitamins and minerals. Stunting can also be caused by unhygienic environments, poor access to health services, and inappropriate care provided by the family. Stunted children are at greater risk later in life of developing coronary heart disease and other noncommunicable diseases. In 2012, stunting affected approximately 162 million children worldwide.

Prevention of stunting, wasting, and micronutrient deficiencies requires permanent improvement in the supply of food, health services, hygienic environments, and human care. Thinness for height, or wasting, is an indicator of acute malnutrition and a strong predictor of mortality. The condition is caused by severe food insufficiency and recurrent or serious illnesses. In 2012, thinness for height affected around 51 million children.

Undernutrition robs the developing world of critical human capital and undermines other development investments in health, education, and economic growth. The 2013

Lancet Series on Maternal and Child Nutrition estimates that undernutrition inhibits countries’ economy by at least 8 percent. This report showed that undernutrition leads to poorer cognition and reduced schooling, which contributes to productivity loss. The World Bank estimates that 2–3 percent of losses in global gross domestic product – \$2 trillion annually – are due to undernutrition and micronutrient deficiencies. Undernutrition can cost individuals up to 10 percent of their lifetime earnings.

USAID research activities have been essential in introducing efficacious measures to reduce undernutrition and simultaneously establishing global evidence on how to tackle this problem effectively and efficiently. Building on prior research findings, USAID aims to reduce stunting in 19 focus countries by 20 percent of the values reported in 2011 by 2016. In order to do so, USAID targets its nutrition programs around three main pathways: 1) the prevention of undernutrition in the critical 1,000-day window; 2) the treatment of wasting in children under 5 through the provision of critical nutrition services and enhancing nutrition competency at the community level and in the health facilities; and 3) promoting an enabling policy environment. The nutrition strategy involves strategic collaboration with development partners working across sectors to scale up programs aimed to improve the well-being of the society as a whole and hence favoring the appropriate development of infants and young children. Key to the nutrition research strategy is

## LIPID-BASED NUTRIENT SUPPLEMENTS

Preliminary Results of the RDNS study suggest that maternal weight loss and stunting was reduced for those participants who received lipid-based nutrient supplements.

Pending a systematic review of more than 70 publications, WHO will develop guidelines designed to impact health policies and interventions that prevent childhood stunting.

2010

2011

2012

2013

2014



A community-based randomized trial in rural Malawi compared lipid-based nutrient supplements. The findings showed that both milk- and soy-based products that were fortified with iron were safe in children.



The Gimbuka Project in Rwanda works to reduce stunting in children under five; children are weighed and measured to assess growth.

improving host country human and institutional capacity to conduct research and use the results to formulate policies and design and monitor programs.

### 1. Multisectoral Approaches to Reduce Stunting and Wasting

Long-term improvements in nutrition can only be achieved through multisectoral approaches that address food security, maternal and child feeding practices, access to clean water and sanitation, provision of health services, and appropriate early child development practices. Further efforts are needed on effective, affordable ways to communicate nutrition information to encourage families to make healthy decisions. One promising approach is the integration

of nutrition education into existing agricultural sector programs that reach families and communities.

Building on a current agricultural extension program in India, a study is using hand-held video cameras to develop participatory, community-based videos that include nutrition education specifically focused on pregnancy and early childhood. Research on the effectiveness and feasibility of this innovation for the promotion of nutrition will help determine if the approach can be easily adapted and scaled through community agents using low-cost, battery-operated pico video projectors (pocket-sized projectors that allow for the display of videos or images) and simple speakers. Nutrition

videos will be uploaded to YouTube, and will also be available for viewing on designated websites. The videos will be periodically transferred to the community-managed pico projectors, completely eliminating the need for connection to electricity or internet.

USAID is also supporting an approach that integrates both nutrition and hygiene into agriculture programs. This strategy is being introduced in projects in Bangladesh, Ethiopia, Uganda, Guatemala, Honduras, and other countries. Results from a qualitative analysis are being used to strengthen this approach for more efficient future uses.

In order to reduce the high prevalence of nutrient deficiencies among women and children, USAID is supporting multi-year, multi-country research in Asia (Bangladesh), Africa (Burundi, Malawi), and Latin America (Guatemala). This research is examining the effect of enhancing diet quality through nutrient-dense food products such as lipid-based nutrient supplements.

As wasting continues to be a priority area, USAID is working with several implementing partners to improve treatment and increase coverage. The Agency supported research to implement and scale up community-based management of acute malnutrition (CMAM) programs. CMAM is an approach to detect early cases of child malnutrition and treat children with ready-to-use nutritional foods and nutrient dense foods. The program has been rolled out in countries across Asia and Africa. To continue CMAM progress, USAID is analyzing tools that allow community workers to more simply identify wasted children, monitor their progress, improve referral for the health-complicated cases, and discharge patients from the program when they have reached their target weight.

### 2. Improved Diet Diversity and Quality

Recent peer-reviewed research has confirmed that women of reproductive age, in many developing countries, are often deficient in vitamin A, vitamin B-12, folate, zinc, iron, and calcium. These deficiencies increase women's risk for mortality at delivery, as well as impair the nutrition content of their breast milk. Nutritional deficiencies can also restrict fetal growth and lead to negative birth outcomes for infants. Furthermore, as a result of poor maternal nutrition, inadequate breastfeeding practices, and insufficient



complementary feeding, children under 5 years of age continue to be significantly deficient in those micronutrients. Agriculture and health programs are coordinating actions in promoting production and consumption of several food groups in order to supply all the required micronutrients. Production and hygienic handling of foods of animal origin that are micronutrient rich, such as eggs, poultry, fish, and milk products, are under attention for creating context-specific value-chain systems.

Moreover, food fortification, which is the incorporation of micronutrients into commonly edible products, such as salt, sugar, oil, and cereal flours, continues to be promoted. USAID-funded studies contributed to the identification of food fortification as one of the most cost-effective mechanisms for improving nutrition when the food vehicles are manufactured by centralized food industries. For this reason, the following foods have been selected for fortification in the noted places: vegetable oil in sub-Saharan Africa; and sugar in Central America, Malawi, Nigeria, and Zambia. Other commonly fortified foods are wheat flour, maize flour, and salt. These fortified vehicles are delivering many micronutrients such as vitamin A, vitamin B-12, folate, iron, zinc, and iodine, which are frequently low in the diets of developing countries. Here, it is interesting to point out that iodine deficiency is kept under control in most countries thanks to the presence of salt iodization programs, which have received the constant attention and support of the U.S. Government in a collaborative endeavor between USAID and UNICEF.

USAID is supporting ongoing studies that are investigating ways of incorporating new micronutrients into fortification formulas of common food vehicles. Other USAID-supported studies are looking at ways to develop practical and simple tools and procedures to support quality control enforcement and monitoring of food fortification programs.

Other novel methodologies that have been studied include using fertilizers to increase iodine and zinc contents in grains. Parboiling (wet cooking prior to milling) of rice is being investigated as a method to increase the micronutrient content of this cereal. Initial findings suggested that this procedure, though possible, only modestly increases the micronutrient content of rice; therefore, more effort is now channeled through

traditional fortification or bio-fortification (natural selection of crop varieties with a higher content of micronutrients). In some countries, USAID-supported studies are assessing the use of micronutrient powders, a type of supplement, to establish "in-home fortification" in communities with limited access to food-based interventions, including food fortification.

Iron/folic acid supplementation continues to be important for pregnant women in order to prevent anemia and reduce the risk of maternal and infant complications. Despite the simplicity of this intervention, it is still affected by programmatic constraints. USAID has continued to work in this area by developing an assessment tool to evaluate distribution of iron/folic acid tablets for pregnant women through their respective health systems. To develop this tool, the Agency drew demographic and health data from multiple countries. Initial country analyses, which was completed in Ethiopia, Malawi, Nigeria, and Uganda, showed patterns in delivery failure of micronutrient supplements and identified opportunities for improvement. Additional countries will be added to the analysis to support an outline of specific recommendations for a quality micronutrient supplement distribution system for maternal anemia programs.

### **3. Measurement Tools**

Many countries with high rates of undernutrition lack access to appropriate, cost-effective technologies and tools to help identify and combat undernutrition. Currently, USAID is testing the effectiveness of new technologies to identify nutritional deficiencies, which is a critical step toward increasing the effectiveness and coverage of nutrition programs. Standardized indicators developed with USAID's support are guiding policy improvements.

USAID is part of an international initiative to take advantage of the household consumption and expenditure surveys that are frequently and systematically executed in many countries to follow changes in income and purchasing practices. These surveys ask about food acquisition and do not measure food intake directly. Small improvements in the surveys might transform them into valuable tools for determining which staple foods have the highest potential for fortification. These improvements might also enable the surveys to be used for estimating the nutrition quality of

the diet in different population strata. This approach has already been used in Nigeria, Uganda, and Bangladesh and the results are promising. The tool might prove useful for formal food intake surveys, though food intake surveys are rarely done because of their complexity and cost.

USAID supports the development of nutrition indicators that effectively measure hunger levels and dietary quality and diversity. These internationally validated measurement tools can better assess baseline conditions in countries and the health impacts of nutrition programs. For example, in countries such as Kenya, Bangladesh, and Mozambique, one set of tools evaluated the nutrition sensitivity of agriculture value chains. The tools assisted each country in designing programs and recognize new ways to impact nutrition outcomes.

Despite the significant negative ramifications of anemia, its assessment is usually limited to times when it is essential for providing the most appropriate treatment. While anemia is usually diagnosed through blood testing, a non-invasive diagnostic procedure would make interventions to correct this condition more efficient and timely. Thus, USAID is supporting research on the effectiveness of a noninvasive anemia screening device for pregnant women and small children. Although preliminary results were less promising than expected for developing-country settings, efforts continue to devise reliable and affordable equipment as well as models for large-scale uptake in targeted countries.

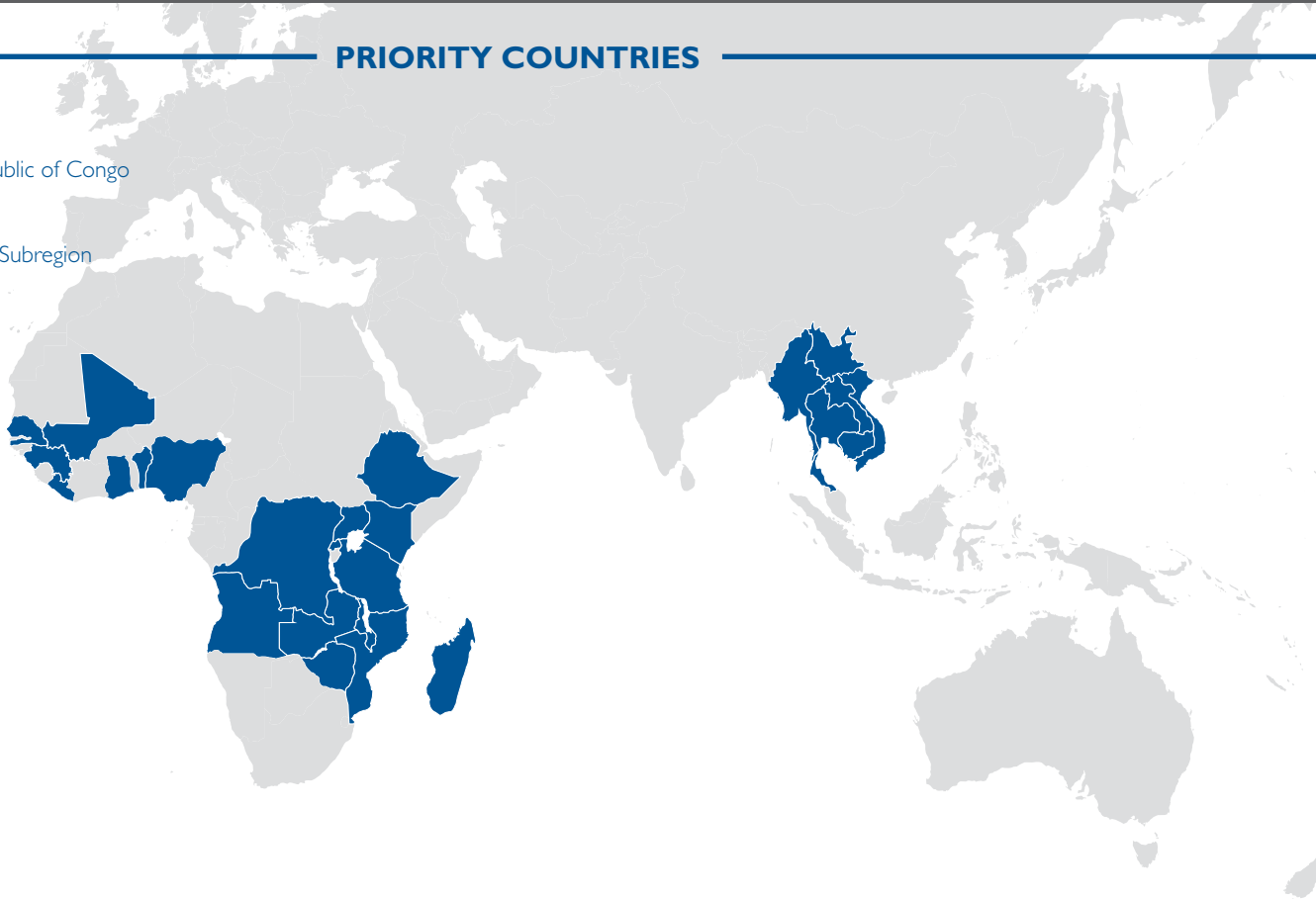
Other tools developed through USAID support helped identify specific nutrient gaps in women's and children's diets and in child feeding practices. This information was used to inform program design to better target social and behavior change communication. Moreover, a modeling tool to substantiate the correlation between low birthweight and the development of noncommunicable diseases in later life will be further validated in 2015 using multiple country data sets. In addition, the Agency continues to support the use of advocacy tools to aid governments in revising policies to address their context-specific nutrition problems.

# MALARIA

*Though the malaria mortality rates in children under 5 years of age were reduced by an estimated 54 percent between 2000 and 2012, there are still more than 1,000 children who die from malaria each day.*

## PRIORITY COUNTRIES

- Angola
- Benin
- Democratic Republic of Congo
- Ethiopia
- Ghana
- Greater Mekong Subregion
- Guinea
- Kenya
- Liberia
- Madagascar
- Malawi
- Mali
- Mozambique
- Nigeria
- Rwanda
- Senegal
- Tanzania
- Uganda
- Zambia
- Zimbabwe

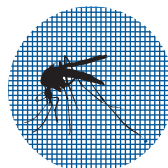


## PMI RESEARCH INVESTMENTS HELP DEMONSTRATE THE EFFECTIVENESS,

USAID funded trials show that mosquito nets, treated with safe insecticide, were effective in significantly reducing child morbidity and mortality and preventing malaria in pregnancy.



The African Summit on Roll Back Malaria issued the Abuja Declaration, which recommended the wide use of treated nets.



Long-lasting insecticide-treated nets (ITNs) are one of the key malaria prevention tools endorsed by WHO.

## HEALTH RESEARCH GOALS

To identify and improve tools to fight malaria, we are committed to:

- **Develop safe and effective vaccines for *Plasmodium falciparum* malaria.**
- **Develop effective and affordable medicines for the treatment and prevention of malaria.**
- **Develop new effective insecticides.**
- **Improve malaria control program implementation and impact.**

## BACKGROUND

According to WHO, the malaria mortality rates in children under 5 years of age in Africa were reduced by an estimated 54 percent between 2000 and 2012. Over the same period, the estimated number of malaria cases in Africa dropped from 174 million to 165 million. Nonetheless, more than 1,000 children still die from malaria every day.

Controlling malaria is an integral part of ending preventable child and maternal deaths. Malaria control is now at a key juncture. Without sustained and vigilant efforts, the great progress made could be quickly reversed, and successful investments in malaria control could be lost.

While current control measures, including long-lasting insecticide-treated nets (ITNs), indoor residual spraying (IRS), intermittent preventive treatment for pregnant women, and prompt diagnosis and treatment with artemisinin-based combination therapies, are highly effective, serious challenges such as insecticide and drug resistance have emerged. New tools, including a highly effective vaccine, novel antimalarial drugs, and innovative vector control methods are needed to further support malaria prevention and control efforts.

USAID is committed to supporting research on these new tools and to answering key operational research questions in cooperation with research partners around the globe and other U.S. Government agencies, such as the U.S. Centers for Disease Control and Prevention, the National Institutes of Health, the Department of Defense, and the Department of Health and Human Services.

### 1. Safe and Effective Vaccines

The vision of the USAID Malaria Vaccine Development Program (MVDP) is the end of malaria as a major global health problem. The current set of malaria prevention and treatment tools are highly effective and have resulted in unprecedented reductions in malaria morbidity and mortality in many African countries. However, as long as conditions remain favorable for its transmission, malaria will resurge if use of these tools is relaxed.

The long-term goal of the MVDP is to develop a highly effective vaccine against clinical malaria that could provide relief from the historic pattern of devastating resurgence-associated morbidity and mortality. While the Phase III field evaluation of a malaria vaccine developed by Glaxo SmithKline was recently completed and will likely become available within a few years, its efficacy is lower than desired (about 25 percent in infants and 50 percent in older children) and declines substantially over time. A more effective and durable vaccine is needed.

There is little doubt that the development of a highly efficacious, durable, and affordable vaccine is possible, but it will require many years to achieve. In the near term, the MVDP aims to provide proof of concept evidence for the feasibility of developing one or more highly efficacious vaccines to enable targeted investment in an ultimately deployable product.

Working with partners, the USAID MVDP currently supports multiple studies on the feasibility of several investigational vaccines against *Plasmodium falciparum*.

### 2. Effective and Affordable Medicines

Antimalarial drug resistance has been one of the greatest threats to malaria control throughout the last 50 years. Resistance to artemisinin drugs, the primary component of artemisinin-based combination thera-

## FEASIBILITY, AND SCALABILITY OF PROVEN NEW TOOLS



Since 2005, PMI has procured more than 123 million ITNs and has funded the distribution of more than 48 million ITNs procured by other donors.

In 2013, USAID funded trials to evaluate second generation ITNs that enhance insecticide activity and potentially mitigate resistance.

\* In 19 focus countries where at least two comparable nationwide household surveys have been conducted since PMI activities were launched, household ownership of at least one ITN increased from a median of 29 percent to 55 percent.



pies, has been documented in the Mekong Subregion, but fortunately it has not yet been confirmed in sub-Saharan Africa. If such resistance were to emerge and spread in sub-Saharan Africa or other malaria-affected regions, it would greatly set back global malaria control efforts.

USAID contributes to the drug development pipeline through its support for the Medicines for Malaria Venture (MMV), a non-profit foundation established in 1999 that supports discovery, development, and delivery of new, affordable antimalarial drugs through effective public-private partnerships. MMV works in partnership with academia, industry, NGOs, international organizations, national malaria control programs, and the private sector to fulfil its mission.

MMV is recognized as the leading product development partnership in the field of antimalarial drug research and development. Over the period 1999–2013, the organization and its partners launched four new antimalarial drugs (Coartem-Dispersible, Eurartesim, Pyramax, and Artesun) and assembled more than 40 research and development projects that are at various points in a pipeline that range from discovery to late-stage development.

Currently, MMV has two novel classes of malaria drugs (OZ439 and KAE609) that have been shown to be efficacious as single drug treatments in Phase II clinical trials and will soon enter Phase II trials in combination with partner drugs. These new treatments offer the greatest hope for an alternative to artemisinin-based combination therapies in the next few years.

### 3. Insecticides for Vector Control

Research and development of new insecticides and insecticide formulations for public health use has become an extremely high priority for the global malaria community. The effectiveness of both long-lasting ITNs and IRS for malaria prevention in many African countries is being jeopardized by the spread and intensification of insecticide resistance, particularly resistance to pyrethroids, which are the only insecticides approved for use on ITNs. Moreover, the number of insecticides that are currently approved for public health use is limited, and no new insecticides have been registered for such use since the mid-1980s.

The Innovative Vector Control Consortium (IVCC) is an international public-private partnership whose aim is to foster research and development of new vector control products and tools for public health. USAID provides support to IVCC to contribute to its insecticide development pipeline, including its work to advance three novel insecticide candidates to the final stages of development by 2019. USAID support covers:

- Advancing two large portfolios of new insecticide development with Bayer and Syngenta, including testing on lead compounds and selection of alternative chemical classes for consideration. Testing encompasses human and environmental toxicology, biological efficacy, cross-resistance, and stability.
- Managing oversight of trials and general administration associated with contracts, meetings, and biannual External Scientific Advisory Committee reviews.
- Publishing of a report that models and details indoor residual spray program costs with different IRS formulations.
- Developing initial cost estimates of different insecticide resistance management strategies.

- Developing a plan for improvement of the regulatory pathway for novel insecticides to reach vector control markets.

### 4. Malaria Control Program Implementation and Impact

USAID, through the President's Malaria Initiative (PMI), an interagency initiative led by USAID and implemented together with the U.S. Centers for Disease Control, complements the more upstream malaria research of MVDP, MMV, IVCC, and other U.S. Government agencies by supporting operational research to help guide its program investments, make policy recommendations to national malaria control programs, and target interventions to increase their cost-effectiveness. As the burden of malaria falls in sub-Saharan Africa, operational research will help programs adjust to the changing epidemiological landscape.

USAID, through PMI, funds operational research across all interventions to improve uptake and scale-up, to preserve intervention effectiveness in the face of resistance, and to assess how to incorporate new interventions and how to adjust interventions in response to changes in Malaria epidemiology. PMI carries out operational research in collaboration with local investigators and institutions, thus strengthening in-country capacity to undertake research. PMI's new Strategic Guidance for Operational Research and list of priority research activities serve to facilitate the identification and prioritization of operational research questions that are important for PMI. External review of this list confirmed that PMI's research priorities are consistent with the priorities of the global malaria research community.



MAGGIE HALLAHAN



Results from operational research studies on existing interventions include:

- In Benin and Ghana, a study to evaluate progress and best practices for scaling up diagnostic testing showed health workers correctly interpreted the results of rapid diagnostic tests almost 100 percent of the time. Malaria microscopy accuracy was above 85 percent in Ghana and 70 percent in Benin. In Benin, more than 90 percent of patients with fever were referred for a diagnostic test while only 60 percent were referred in Ghana. PMI is working with counterparts in Ghana and Benin to refine and strengthen training, supervision, and quality assurance activities to address the noted deficiencies.
- In Tanzania, a PMI-supported study to understand the impact of combining IRS and ITNs on malaria transmission demonstrated that IRS provided additional protection against malaria in this context

as compared with ITNs alone, adding to the global knowledge base on combining vector control interventions.

PMI-funded studies addressing challenges to malaria control, new methods, and promising interventions include:

- Studies to address the growing issue of pyrethroid resistance. For example, one such study in Mali is evaluating the effectiveness of second generation long-lasting insecticide nets that use a synergist to enhance insecticide activity. Another study is looking at second generation non-pyrethroid durable wall liners in Tanzania to determine their potential as an effective alternative to IRS.
- Studies to determine the effectiveness of promising new interventions like intermittent mass screen and treat (IMSaT) are being conducted in western Kenya, an area with persistently high malaria

transmission, despite scale-up of interventions. IMSaT involves periodically testing all people living in areas with malaria transmission and providing treatment to people infected with malaria parasites. IMSaT is expected to reduce malaria transmission because once a person's infection is cleared by treatment, they cannot infect a mosquito that bites them. In addition, in Mali and Senegal, studies are underway to evaluate the operational feasibility of scaling up seasonal malaria chemoprevention. Seasonal malaria chemoprevention is the intermittent administration of full treatment courses of an antimalarial medicine to children during the malaria season, in areas of highly seasonal transmission. The goal of seasonal malaria chemoprevention is to reduce malarial illness by maintaining therapeutic antimalarial drug concentrations in the blood throughout the period of greatest malarial risk.



# AIDS-FREE GENERATION

As a key implementing agency for the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), USAID has been at the forefront of the global AIDS response. From the earliest stages of the pandemic in the 1980s through the 2003 establishment of PEPFAR, USAID's investments in HIV and AIDS research have been an important contribution toward an AIDS-free generation.

USAID is using implementation science to drive results and enhance translation of HIV and AIDS research into programmatic impact for populations at risk. This model also allows researchers and program implementers to use research findings to

examine the feasibility of integrating innovative ideas within existing programs and also to identify key linkages that will improve prevention programs, care and treatment options, and patient retention.

Biomedical science is also integral to advancing HIV and AIDS prevention methods and technologies. More than two decades worth of investments with partners like the International AIDS Vaccine Initiative have helped strengthen clinical research capacity in regions most devastated by the epidemic. USAID-funded trials have provided the first proof of concept that the vaginal microbicide gel, tenofovir, could safely reduce the risk of HIV transmission from men

to women. Clinical trial research funded by USAID has also supported packaging for home administration of nevirapine, a drug for the prevention of mother-to-child transmission (PMTCT) of HIV. In addition, research on voluntary medical male circumcision, a cost-effective biomedical intervention that has demonstrated the ability to significantly reduce infections, has potentially averted millions of dollars in HIV treatment and care.

Read further to learn more about Bureau for Global Health efforts in behavioral, biomedical, and operations research in HIV and AIDS.



# HIV and AIDS

*There are 20 percent fewer infections now compared to 10 years ago. However, an estimated 2.5 million people continue to be newly infected with HIV every year in sub-Saharan Africa, where 1 in 20 adults is living with HIV.*

## FIELD RESEARCH SITES

- Botswana
- Burkina Faso
- Cameroon
- Cote d'Ivoire
- Dominican Republic
- Ethiopia
- Georgia
- Ghana
- Guatemala
- Haiti
- India
- Kenya
- Lesotho
- Malawi
- Mali
- Mozambique
- Namibia
- Nigeria
- Pakistan
- Rwanda
- Senegal
- South Africa
- Swaziland
- Tanzania
- Togo
- Uganda
- Vietnam
- Zambia
- Zimbabwe



## ILLUSTRATION OF USAID RESEARCH INVESTMENTS IN

2009

2010

2011

2012



The CAPRISA 004 trial found that using a vaginal microbicide gel before and after sex containing 1% tenofovir reduced HIV acquisition by 39% in South African women. This was the first proof of concept in humans for efficacy of topical microbicides.

USAID developed a "Shared Vision and Strategic Plan for Microbicide Introduction" in preparation for bringing a microbicide product to market.

## HEALTH RESEARCH GOALS

To improve treatment services and reduce rates of infection and transmission of HIV and AIDS, we are committed to:

- **Develop and introduce microbicides for women to reduce the risk of HIV infection.**
- **Accelerate the development of clinical testing of novel HIV vaccine candidates.**
- **Strengthen the evidence base to improve HIV and AIDS prevention, care, and treatment programs.**

## BACKGROUND

Great strides have been made in combating the HIV and AIDS pandemic. With 20 percent fewer infections now than 10 years ago, HIV and AIDS is sharply declining in some regions. However, an estimated 2.3 million people continue to be newly infected with HIV every year. In sub-Saharan Africa, 1 in 20 adults is living with HIV, and in the Middle East and North Africa, new infections have increased by over 35 percent in the last decade. Women and girls account for more than half of the 34 million people living with HIV worldwide.

While no single approach to HIV and AIDS prevention is likely to have a sufficient impact, integrated behavioral, biomedical,

and structural interventions could yield the best results. Though several effective HIV prevention methods are available, the need to develop and evaluate novel technologies and evidence-based strategies is as urgent as ever if the course of the pandemic is to be reversed and an AIDS-free generation achieved.

USAID's research agenda contributes to the HIV and AIDS response and continues to harness USAID's extensive health and development expertise to maximize the reach of technically sound, cost-effective, and sustainable HIV and AIDS interventions. Through 2014, USAID will continue to collaborate with key partners dedicated to the development of an HIV vaccine and effective microbicides while furthering the existing evidence base to improve HIV and AIDS prevention, care, and treatment programming. USAID supports the development of safe, effective, acceptable, and affordable microbicide candidates, including two advanced leads in Phase III trials. USAID also funds novel microbicide delivery approaches and multipurpose microbicides in the hopes of bringing diverse options to market for women.

The development and testing of novel HIV vaccine candidates for global use remains a high priority. HIV vaccine research and testing, which is supported by long-term epidemiological studies and research into access and policy issues, is strengthening clinical trial and laboratory capacity in developing countries. Through implementation science, USAID is improving access to and quality

and effectiveness of HIV and AIDS prevention, treatment, care, and support programs in developing countries. Implementation research and program evaluations identify and address gaps in knowledge and increase the evidence base for scaling up and improving programs.

## I. Microbicides for Women to Reduce the Risk of HIV Infection

Women make up almost 60 percent of new infections in sub-Saharan Africa. In many countries, women lack the power to negotiate the use of currently available prevention tools and approaches to protect themselves against HIV. There is a need for new HIV prevention methods that women can control on their own.

In 2010, the USAID-funded trial conducted by the Center for the AIDS Program of Research in South Africa (CAPRISA 004) provided groundbreaking proof of concept that 1 percent tenofovir gel can safely and effectively reduce a woman's risk of HIV infection. A confirmatory trial, the Follow-on African Consortium for Tenofovir Studies (FACTS) 001 trial, using the same application regimen as in CAPRISA 004, is helping to achieve regulatory approval for this microbicide product. Now in its third year, FACTS 001 is being conducted at nine trial sites in South Africa. This trial is supported by USAID in partnership with the South African Department of Science and Technology and the Bill & Melinda Gates Foundation. Results of the trial are expected in 2015.

## HIV AND AIDS MICROBICIDES RESEARCH



FACTS001 trial launched in 2011. Additional phase III efficacy trials are continuing, using dosing strategies that may be more acceptable to young women, including the FACTS 001 trial of tenofovir gel before and after sex, as well as two phase III trials of a long-acting monthly vaginal ring releasing the antiretroviral agent dapivirine. There is optimism that one or both of these microbicides will be a powerful HIV prevention tool for women. Results of the FACTS study are expected in early 2015, and trials of dapivirine ring by 2016.

2013

2014

2015

2016



New microbicide delivery systems that will be more acceptable, easier to use, and less costly are in development. Products like fast dissolving vaginal tablets and vaginal rings will have the ability to combine both contraceptive and anti-HIV activities.



With the unprecedented opportunity in the next 5 years to obtain regulatory approval from the U.S. Food and Drug Administration for 1 percent tenofovir gel, there is an urgent need to plan for the introduction of this new prevention product in countries where it will have the greatest impact. With USAID collaboration, a new public-private joint venture is being explored to register, manufacture, and distribute 1 percent tenofovir gel in various

peri-coitally-applied product. Results of the trial are expected in 2016.

Other enhanced formulations, dosing regimens, and delivery systems for long-acting and on-demand methods are also being developed and tested. These enhancements may prove to be more acceptable and easier to use and, as a result, more effective. They may also reduce the anticipated cost of microbicides. New formulations and delivery

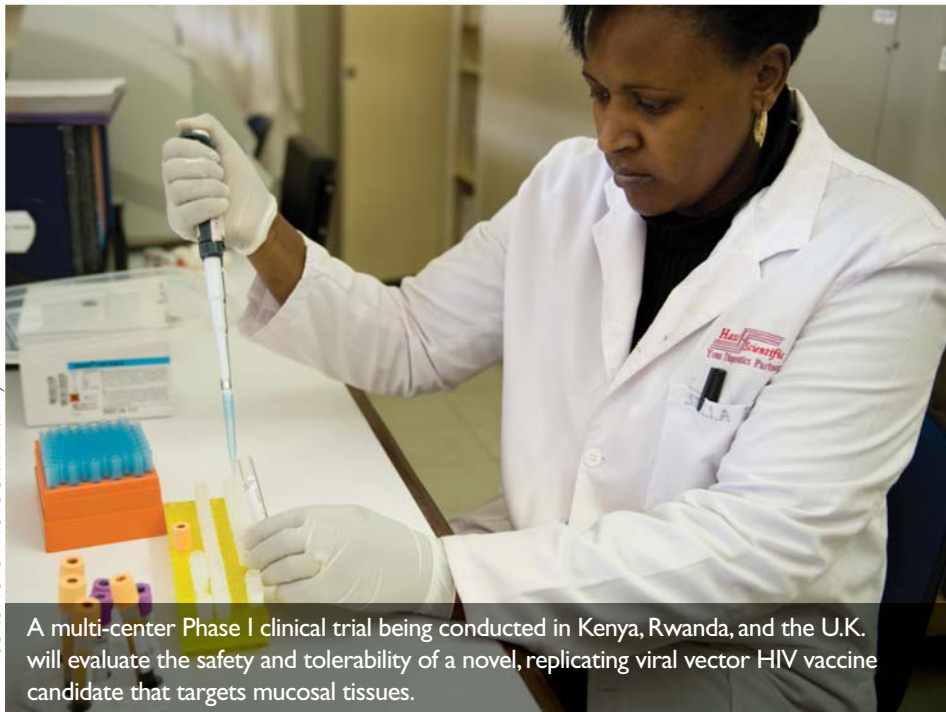
and for Phase I, II, and III clinical trials. These results help USAID ensure that its resources are used as effectively as possible.

## 2. HIV Vaccine Candidates

USAID supports the International AIDS Vaccine Initiative (IAVI) to strengthen clinical trial capacity in developing countries, enrich the pipeline and advance the development and testing of novel AIDS vaccine candidates, and analyze policy and future access issues through a cooperative agreement. Building on its longstanding partnerships in Africa, IAVI is increasing local scientific leadership and ownership, improving sustainability of advanced research capacity established at the African Clinical Research Centers, and helping to train the next generation of investigators to ensure that the research agenda is focused on developing a vaccine that is safe, effective, and accessible to those who need it most.

IAVI is in the midst of a Phase I clinical trial of the novel Sendai vector AIDS vaccine candidate, currently ongoing in Kenya, Rwanda, and the United Kingdom (see page 37). The Sendai vector, developed with USAID support, retains the ability to multiply inside the human body and might be able to elicit immune responses that are broader, longer lasting, and more potent. The Sendai candidate, which is delivered nasally, also targets immune response to mucosal tissues, where HIV establishes a foothold in the earliest stages of infection; this could prove to be a more effective route of preventing HIV infection. Data from this study will determine whether IAVI and its partners continue to develop this candidate vaccine regimen, and a decision is expected in late 2014.

IAVI continues to advance its broadly neutralizing antibody (bNAb) program and has begun translating lessons from its observational epidemiological work into clinical trials. The A003 Phase I clinical trial is the first trial in humans to use a broadly neutralizing antibody identified by IAVI and partners in its Neutralizing Antibody Consortium as part of Protocol G, a landmark study supported by USAID to identify such antibodies in HIV-infected volunteers. This trial tests a novel concept to deliver a vector carrying genetic instructions for producing a bNAb; it could provide a preliminary indication of whether this technique can be used to prevent HIV infection. Initial data on immunology of the neutralizing antibody



SOKOMOTO PHOTOGRAPHY/IAVI

A multi-center Phase I clinical trial being conducted in Kenya, Rwanda, and the U.K. will evaluate the safety and tolerability of a novel, replicating viral vector HIV vaccine candidate that targets mucosal tissues.

African countries. USAID and its partners are building on the Agency's Proposal for a Shared Vision and Strategic Plan for Microbicide Introduction to prepare for the introduction and access programs that will be needed. The Agency is also initiating related implementation research studies. This includes the CAPRISA 008 study, supported jointly by USAID and South Africa, to compare the use of 1 percent tenofovir gel when provided in a clinical trial setting with its use when provided in a more typical family planning program setting.

A Phase III clinical trial, The Ring Study, is under way in South Africa and Uganda to test the monthly dapivirine vaginal ring with support from USAID and other donors. This trial is the first time a non-gel microbicide delivery system is being tested for effectiveness in women. The long-acting ring may be more acceptable and easier for some women to adhere to than a daily-use or

systems include a 90-day tenofovir vaginal ring, a biodegradable implant, and a fast-dissolving vaginal tablet.

Microbicide candidates that have multipurpose prevention activity are also in development and may be very attractive to potential users and providers. In addition to providing protection against HIV infection, these microbicide candidates may, for example, protect against other sexually transmitted infections and unwanted pregnancies. Early testing has begun on vaginal rings that combine both contraceptive and anti-HIV activity.

To better predict when a new microbicide candidate warrants the investment required for advanced product development and testing in Phase III clinical trials, USAID continues to collaborate with its partners and other donors to design and validate improved models for preclinical evaluation

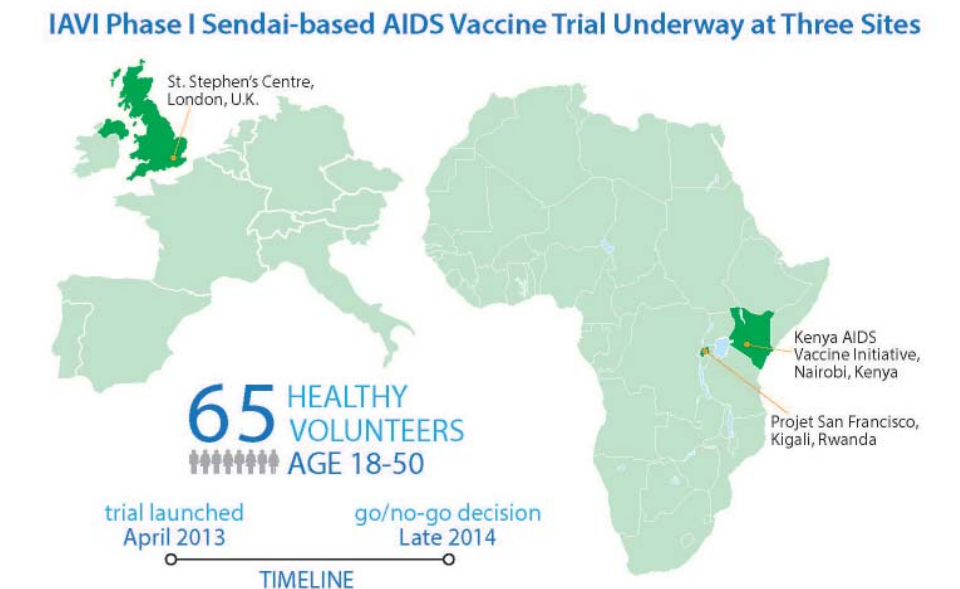
response and potential new targets for vaccine design are expected in late 2014.

The fishing communities of Lake Victoria represent a key underserved population in the fight against HIV. In Uganda, IAVI and partners conducted a targeted mapping and survey to collect current data on socio-demographic characteristics, household composition, structures and dwelling characteristics, and current HIV rates in selected fishing communities. The objectives of this work were to determine and characterize HIV prevalence, incidence, and risk profiles and also to evaluate potential follow-up/retention rates and willingness of the communities to participate in future clinical trials related to HIV vaccines and other new prevention technologies. In order to better understand the health status and needs of the Lake Victoria population, in 2013, IAVI and partners launched the Lake Victoria Health Research Consortium, a collaborative research group of local organizations in Kenya, Tanzania, and Uganda.

With support from USAID, IAVI worked with the AIDS Vaccine Advocacy Coalition: Global Advocacy for HIV Prevention and the Futures Institute to expand on UNAIDS data analysis to model the impact of adding an AIDS vaccine and other new prevention technologies to existing treatment and prevention options. The analyses show that even if access and adherence to existing options were maximized, low- and middle-income countries would still see more than half a million new HIV infections a year come 2050. Adding a 60-percent-efficacious vaccine on its own could further reduce new infections by 25 percent in its first decade and by almost half in 25 years averting up to 22 million infections. Further analyses underway will help researchers better understand the parameters that will influence the cost-effectiveness of future AIDS vaccines, which will be critical to ensuring that future vaccines are accessible to those most in need.

### 3. Improving HIV and AIDS Prevention, Care, and Treatment Programs

The first phase of PEPFAR focused on reducing HIV mortality and morbidity as quickly as possible. The main priority of the emergency response in the first phase was rapid scale-up of HIV and AIDS service delivery programs. Building off the first phase, the second phase of PEPFAR focuses on increasing the sustainability, cost-effectiveness,



and impact of HIV and AIDS programs. Adopting approaches that increase the impact of HIV and AIDS programs and make them more sustainable and cost-effective will ensure the continuation of long-standing, locally owned HIV programs in the countries that are hardest hit by the epidemic. In order to achieve these outcomes, PEPFAR embraces an "implementation science" framework to improve the uptake, translation, and implementation of research into service delivery practices. USAID's implementation science agenda emphasizes methodological rigor, programmatic context, and sound scientific principles in support of HIV and AIDS prevention, care, and treatment research. Ongoing implementation research and program evaluations aim to provide local implementing partners, donors, and national governments with the evidence base to improve HIV and AIDS services and to inform policy.

In 2012 and 2013, USAID awarded more than \$20 million to support 10 implementation science studies in nine countries. Through these studies, USAID seeks to answer critical questions across a range of program areas and populations so that program integration across the HIV prevention, care, and treatment continuum could be strengthened. The studies' findings will contribute to the evidence base for HIV programs and will maximize the impact of program investments around the world. Data gathered will help partner countries support their efforts to prevent new infections and save lives.

A multi-country demonstration study in Kenya and Uganda is evaluating implementation of antiretroviral treatment (ART) and pre-exposure prophylaxis (PrEP) as a "bridge" to treatment for HIV prevention in heterosexual serodiscordant couples. The findings will inform ongoing policy discussions about how to best incorporate PrEP and ART into HIV prevention strategies. Another study in South Africa examines how to increase timely entry-into-care among people recently diagnosed as HIV positive by examining four strategies that address key barriers to timely initiation of ART, including health perceptions, personal barriers, and structural barriers. The findings will strengthen care and treatment programs by identifying effective approaches to reducing late initiation of HIV treatment.

USAID is supporting research and evaluations to improve coverage, quality, and effectiveness of HIV and AIDS treatment and prevention programs. These include:

- The Research to Prevention (R2P) Project supported research to identify the most effective interventions for preventing HIV and improving HIV prevention programs in the countries most affected by the HIV epidemic. R2P sought to achieve this goal by conducting operations research and program evaluation, promoting the utilization of data in program design, and building local research capacity. R2P ended in March 2014 after completing more than 30 studies and activities. A study on economic interventions for urban young people



IAVI and partners conduct epidemiological research in fishing communities along Lake Victoria where HIV incidence rates are several times higher than the national average.

as a means of HIV prevention provided evidence that a cash incentive could promote uptake of clinical visits and that the intervention was feasible to implement without risk of significant negative consequences. Another mixed-methods longitudinal study evaluated a multi-level HIV prevention intervention for female sex workers living with HIV and their regular male partners. This study showed that program participants increased their condom use and decreased their number of sexual partners. This study also demonstrated improved retention

in HIV care and adherence to ART for participants in the multi-level intervention. Finally, results from a multi-country study called the Systematic Monitoring of Voluntary Medical Male Circumcision Scale-up in Eastern and Southern Africa showed that safe, high-quality voluntary medical male circumcision can be implemented and sustained at scale via a number of efficiency elements.

- The HIVCore Project supports research that seeks to improve the efficiency, effectiveness, scale, and quality of HIV and

AIDS treatment, care, and support as well as PMTCT programs by conducting operations research and focused evaluations and by promoting the use of research findings. HIVCore will end in September 2016 and anticipates having more than 20 different studies completed by that time. Results from a multi-country assessment include findings that increase our understanding of how to make HIV programming more inclusive for persons with disabilities as they experience greater sexual vulnerability to HIV; lack access to HIV prevention, care, and treatment services; and experience stigma that affects utilization of HIV services. Results from a nationally representative assessment of clinics in Côte d'Ivoire identified the causes for loss to follow-up and delays throughout the PMTCT cascade. These findings will be used to help inform the country's Option B rollout.

- The Gender-based Violence (GBV) Program Evaluation, Tathmini GBV, identifies and addresses gaps in GBV prevention and service delivery through intensive monitoring and evaluation of GBV programs. It provides tools and methods to evaluate promising service delivery and community-based intervention models for GBV prevention and related HIV outcomes. The activity strengthens collaboration with local partners to bolster the evidence-base for improving and scaling up effective GBV programs worldwide.



# PROTECTING COMMUNITIES FROM INFECTIOUS DISEASES/ GLOBAL HEALTH SECURITY AGENDA

For decades, USAID has been a leader in the control and prevention of infectious diseases. Through the Bureau's investments in Tuberculosis and Global Health Security and Development, there is increased ability to identify and respond to disease threats. Research partnerships designed to address target populations have helped alleviate the burden of diseases like multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis and have also helped communities and governments prepare for and prevent the spread of emerging diseases like Middle East Respiratory Syndrome Coronavirus and H7N9 Avian Influenza.

As part of the U.S. Government Global Health Security

Agenda, USAID is using research investments to protect communities from infectious diseases. The Agency therefore supports the strengthening of local capacity by working to understand country hotspots – zones where the risk of infection spillover, amplification, and spread are greatest. In collaboration with U.S. Government and international partners – the U.S. Centers for Disease Control, Department of Defense, U.S. State Department, WHO, and Food and Agriculture Organization of the United Nations – USAID has assisted in strengthening local-laboratory capacities in 20 countries. Through this same collaboration, regional networks in Africa, Asia, and 25 veterinary and public health schools are engaged to train students, including future researchers, on how to address emerging disease threats.

In addition, through partnerships with host country governments and the private sector, USAID research investments have contributed to significant declines in tuberculosis (TB) prevalence in the Agency's priority countries.

Research on the introduction, health system requirements, and impact of diagnostic tools that are designed to rapidly detect TB has the potential to be a game-changer for TB screening in lower- and middle-income countries.

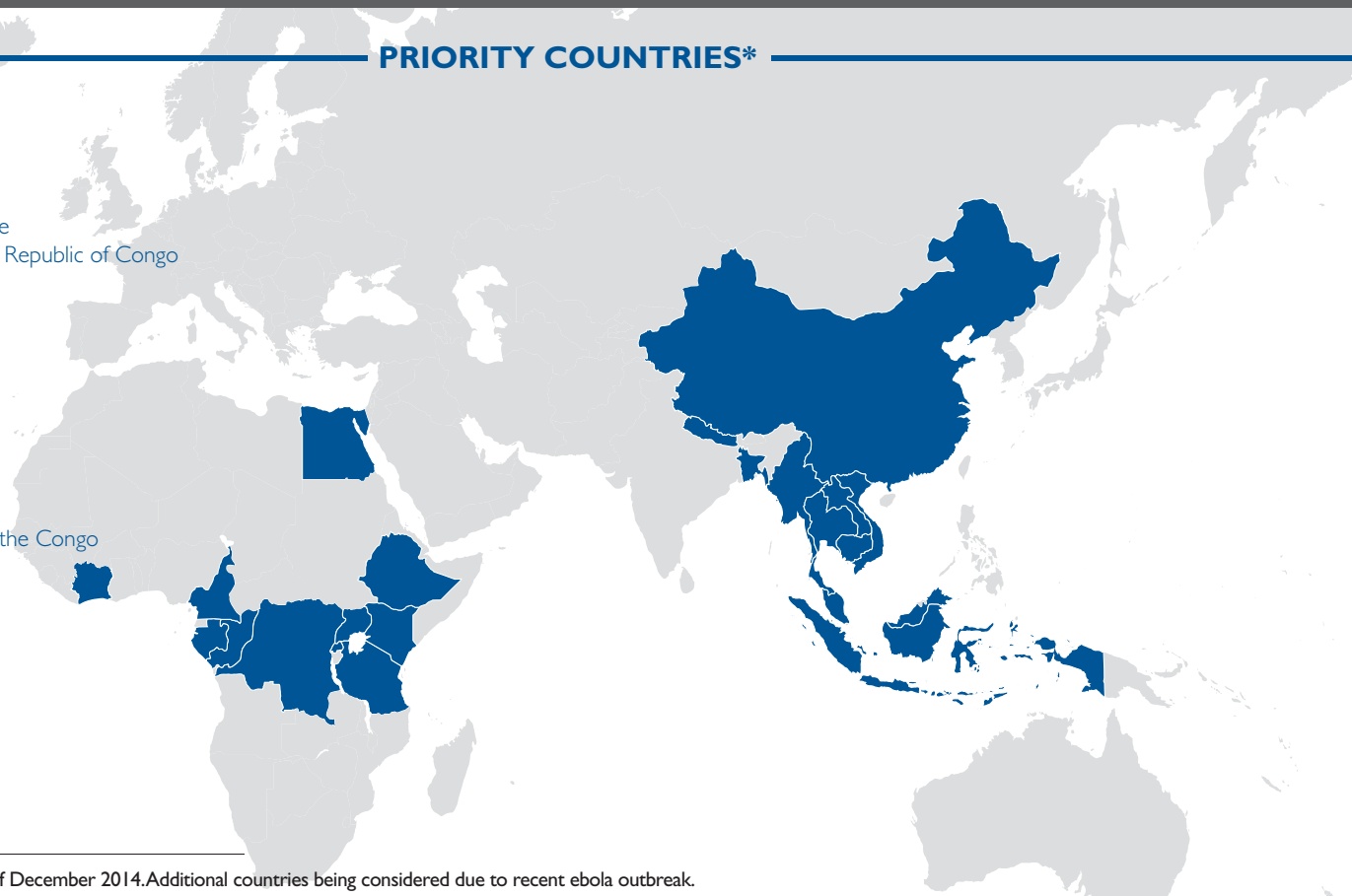
This section highlights research investments that address global health security related to infections from global pandemics and tuberculosis.

# GLOBAL HEALTH SECURITY AND DEVELOPMENT

The recent emergence and spread of diseases, such as H7N9 avian influenza, Middle East Respiratory Syndrome Coronavirus, and ebola in West Africa, serve as clear reminders of how vulnerable the increasingly interconnected world is to zoonoses – diseases that can be transmitted to humans from animals.

## PRIORITY COUNTRIES\*

- Bangladesh
- Cambodia
- Cameroon
- China
- Cote d'Ivoire
- Democratic Republic of Congo
- Egypt
- Ethiopia
- Gabon
- Indonesia
- Kenya
- Laos
- Malaysia
- Myanmar
- Nepal
- Republic of the Congo
- Rwanda
- Tanzania
- Thailand
- Uganda
- Vietnam



\* List current as of December 2014. Additional countries being considered due to recent ebola outbreak.

## USAID RESEARCH INVESTMENTS THAT SUPPORT

Avian influenza program is launched. USAID has strengthened capacities in more than 50 countries across Latin America, Africa, and Asia to prevent, detect, and control H5N1 avian influenza.

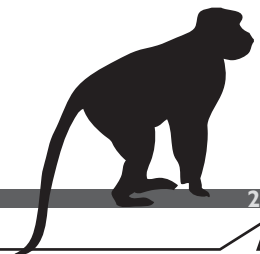
2005



Pandemic preparedness activities are started. USAID has supported 30 countries in Africa and Asia to establish national coordinating bodies for pandemic preparedness.

2007

2008



2009

Emerging Pandemic Threats I program is launched with a focus on wildlife. About 75 percent of new human diseases are caused by microbes that originate in animals. USAID has supported disease surveillance, risk mapping and outbreak response in countries where new disease threats are most likely to emerge from animal populations.

## HEALTH RESEARCH GOALS

To strengthen pandemic detection and response methods, we are committed to:

- **Develop and introduce surveillance methods to increase pathogen detection.**

- **Develop and test methods to improve the understanding of risk, including how human behavior contributes to the risk of disease emergence.**

## BACKGROUND

The recent emergence and spread of diseases such as H7N9 avian influenza, Middle East Respiratory Syndrome (MERS) Coronavirus, and Ebola in West Africa serve as clear reminders of how vulnerable the increasingly interconnected world is to zoonoses diseases that can be transmitted to humans from animals. Because these diseases can quickly surface and spread, they pose serious concerns to public health, economic, and development sectors.

To protect against the potential consequences associated with emergence of a pandemic threat, comprehensive disease detection and response capacities are needed, especially in locations where threats are most likely to emerge.

USAID's Global Health Security and Development Program seeks to aggressively preempt and combat diseases that could spark future pandemics. Since 2009, USAID has been a leader in supporting surveillance of high consequence viral families circulating in targeted animal taxa living in Africa, Asia, and South America. USAID couples this information with social science research describing behaviors and practices that evoke viral spillover and spread from animals to humans. In addition, USAID is building the capacity of national workforces to use this information to earlier detect and respond effectively to future threats.

In September 2014, the Emerging Pandemic Threats 1 Program came to a close. During summer 2014, data collected during the 5-year program underwent analysis, and reports will be developed that speak to the areas of research focus.

In November 2014, the Global Health Security and Development Unit launched the Emerging Pandemic Threats 2 Program. This next iteration builds on the knowledge gained under Emerging and Pandemic Threats 1 and will continue to investigate surveillance methods and improve the understanding of risk associated with the emergence and spread of pandemic threats.

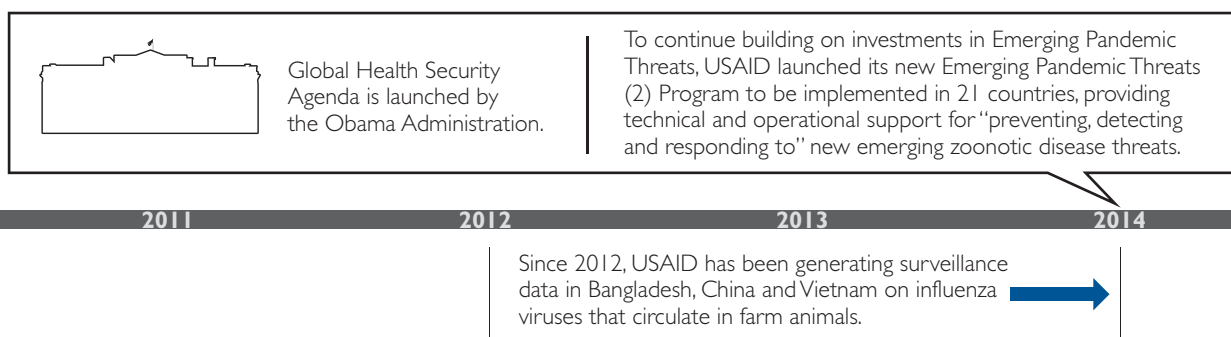
Also, in February 2014, the Obama Administration launched the Global Health Security Agenda. In an effort to promote a "world safe and secure from global health threats posed by infectious diseases," the

Global Health Security Agenda comprises nine objectives aimed at: (1) preventing and reducing the likelihood of outbreaks; (2) detecting threats early; and (3) responding effectively and rapidly to outbreaks. USAID's Global Health Security and Development Unit represents the development arm of the Global Health Security Agenda and contributes to all nine of its objectives. USAID inherently believes that understanding disease emergence and developing better surveillance methods is paramount to success in this realm.

## 1. Strengthening Surveillance Methods

USAID continues to generate new surveillance data on microbes circulating in wildlife populations, with highest priority given to rodent, bat, and nonhuman primate species. To date, more than 50,000 animals have been sampled in 20 countries on three continents – South America, Africa, and Asia – where new pandemic threats are likely to occur. Using a newly developed set of viral pathogen detection protocols, as well as a global network of laboratories, 315 novel viruses in families known to cause epidemics have been discovered. These protocols have also been used to characterize two current pandemic threats: H7N9 avian influenza and MERS Coronavirus. This information feeds into a global database and contributes to mapping microbial distribution and characterizing the risk associated with different human/animal interactions. Information is becoming publicly available at <http://www.healthmap.org/predict/>. This

## GLOBAL HEALTH SECURITY AND DEVELOPMENT



## SIGNIFICANT RESEARCH ACHIEVEMENTS

- The PREDICT project discovered a SARS-like virus in bats that could potentially infect people.
- Through the human-animal exposure study in Laos, the PREVENT project highlighted the importance of social factors – ethnicity, gender, and age – on human exposure to animals. These behavioral findings lay a foundation for exploring strategies to prevent or mitigate opportunities for zoonotic disease spillover.
- Research on MERS Coronavirus has demonstrated that camels can be infected and shed the virus, indicating that human-camel contact may be the source of some human cases.

website and USAID's PREDICT project have been recently chosen for display in the 2014 iteration of the Places & Spaces: Mapping Science exhibit on the topic of "The Future of Science Mapping." Places & Spaces has featured the best examples of novel mapping and data visualizations for 10 years, and selections from the exhibit are being archived in well-known collections such as in the Library of Congress.

In Brazil, Uganda, and Malaysia, ongoing research is investigating pathogen diversity across different types of settings (urban,

peri-urban, and undeveloped). This study will help clarify the impact of human activity on wildlife and microbial diversity and provide some initial insight into how those settings provide new opportunities for animals and humans to interact.

USAID continues to generate surveillance data in Bangladesh, China, and Vietnam on influenza viruses circulating in farmed animals, including swine, poultry, and wild birds. This information will shed light on the distribution, diversity, seasonality, and evolution of a family of viruses that has caused four pandemics in the past century.

### 2. Improving the Understanding of Risk and Role of Behavior

In high-risk areas for pandemic threats, often the specific practices of communities and industries such as the oil, gas, and mining sectors put people at risk. To protect against potential pandemics, it is necessary to systematically identify high-risk areas and practices, as well as how these activities can be changed.

By re-analyzing the "hotspot" maps of high-risk areas with new datasets, USAID's implementing partners found a stronger relationship between disease emergence risk, human population growth, and regions rich in wildlife. New high-resolution risk maps have been produced to provide subnational information on the highest risk areas.

These maps not only show that the underlying drivers of diseases vary by region, but

also indicate that diseases emerge primarily from land use changes, agricultural intensification, and associated secondary factors (e.g., bushmeat hunting and consumption) in locations with the most zoonoses.

USAID is assembling the most comprehensive and detailed information available to date on zoonotic disease emergence using local findings that show that the highest risk of disease transmission is associated with human and domestic animal interaction with wildlife, such as interactions in wildlife hunting, animal crop raiding, and wildlife consumption practices. The data are used to guide surveillance, prepare for pandemics, and develop disease prevention and control strategies.

USAID is also conducting in-depth research to locate high-risk populations and identify social preferences, customs, and behaviors that are linked with risky contact between humans and animals. For example, USAID projects are characterizing the wild animal meat trade and the level of biosecurity infrastructure existing in markets in Indonesia, Laos, Vietnam, the Democratic Republic of Congo, and the Republic of Congo. This research is being used to understand the amount and types of wild animal meat that move through the markets and value chain and how the meat is handled. Ultimately, this information will allow for the development and testing of interventions that reduce risk.



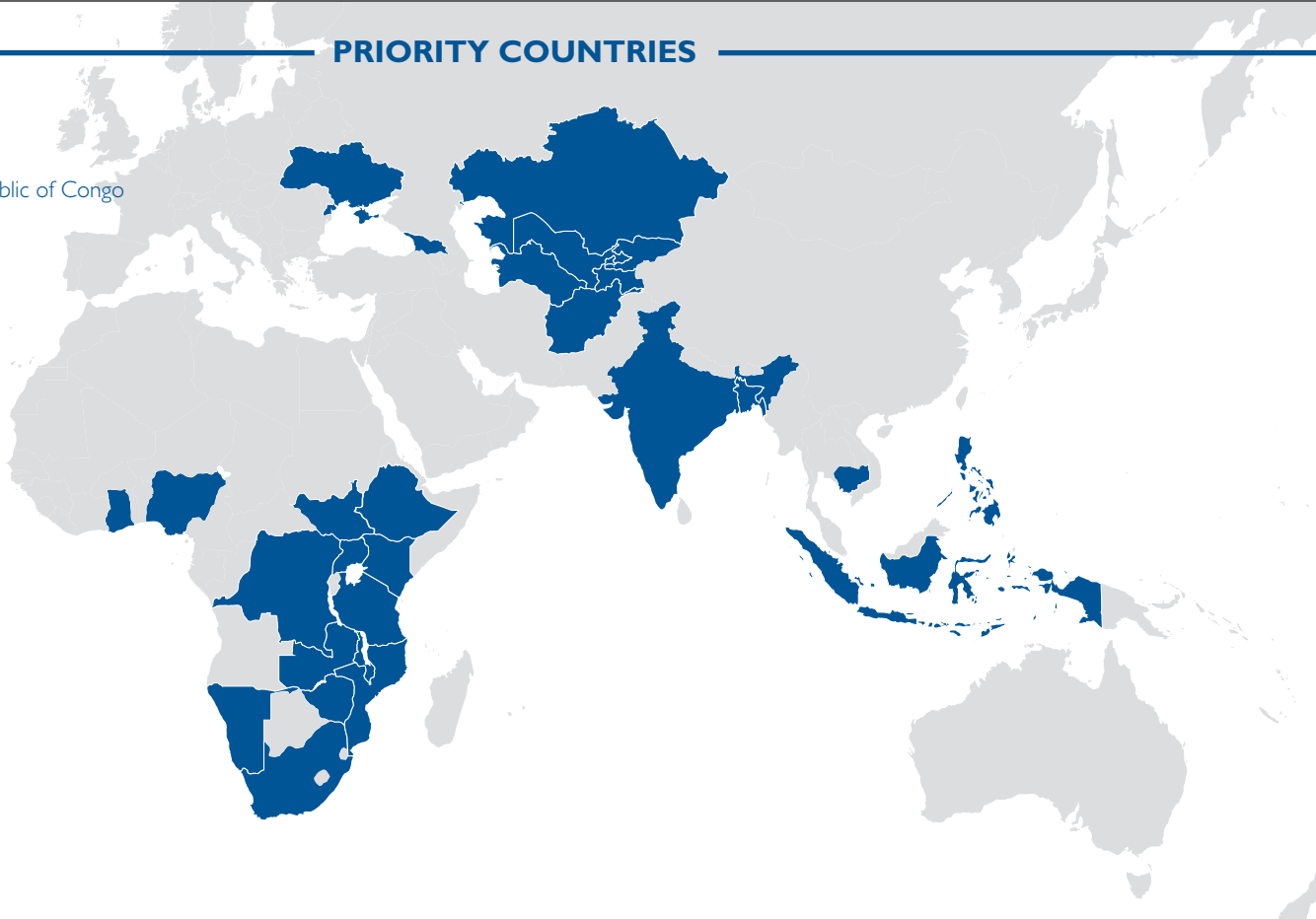


# TUBERCULOSIS

Despite advances in TB prevention and treatment, progress in controlling and eliminating TB continues to be hampered by lack of simple point-of-care test that can quickly detect TB and MDR-TB, unavailability of effective and well tolerated treatments for TB and MDR-TB, and the absence of a vaccine to prevent new TB cases.

## PRIORITY COUNTRIES

- Afghanistan
- Bangladesh
- Cambodia
- Democratic Republic of Congo
- Ethiopia
- Georgia
- Ghana
- India
- Indonesia
- Kazakhstan
- Kenya
- Kyrgyz Republic
- Malawi
- Mozambique
- Namibia
- Nigeria
- Philippines
- South Africa
- South Sudan
- Tajikistan
- Tanzania
- Turkmenistan
- Uganda
- Ukraine
- Uzbekistan
- Zambia
- Zimbabwe



## USAID RESEARCH INVESTMENTS



Clinical trials to compare 6-month versus 8-month treatment for TB showed that 8-month regimens were significantly inferior to the 6-month standard regimen. The results have since then been included in *International Standards of Care for TB Treatment*.

1996 1997 1998 1999 2000 2001 2002 2003 2004



Research showed that community participation in care was cost-effective and beneficial to patients and affected communities.



## HEALTH RESEARCH GOALS

To target tuberculosis detection, diagnosis and management, we are committed to:

- Evaluate diagnostic tools to more effectively detect TB in individuals with and without HIV.
- Develop regimens that improve the treatment of MDR-TB.
- Conduct operations research for improving TB program performance and management of TB-HIV co-infection.

## BACKGROUND

According to the World Health Organization Global Tuberculosis report, there were 8.6 million new tuberculosis (TB) cases in the world and 1.3 million TB-related deaths in 2012. Of these 8.6 million new cases, about 2.5 million were not reported and/or started on TB treatment. During the same period, there were also 450,000 new cases of multidrug-resistant TB (MDR-TB) among all the notified TB cases, and only 21 percent of these cases were on treatment.

Despite these shortfalls there has been major progress toward global targets related to the reduction of the burden. TB mortality rate has declined by 45 percent since 1990, and the number of

new TB cases has been falling at the rate of 2 percent a year:

Overall TB prevention and care continues to be hindered by the lack of rapid and point-of-care diagnosis tools that can detect TB and MDR-TB in adults and children, particularly for HIV-positive individuals. Moreover, efforts continued to be undermined by the lack of vaccines to prevent new cases and the lack of more effective and well tolerated drugs that can shorten treatment courses. This includes treatment for MDR-TB, that can be taken in conjunction with antiretroviral drugs for HIV.

USAID is investing in research activities that aim at improving the detection and treatment of TB, preventing ongoing TB transmission, and strengthening delivery of service.

### I. TB Diagnostic Tools

In response to the availability of new diagnostic tools, USAID through the TREAT TB project is supporting studies that would assess the real-world performance of these new tools and provide national-level policy-makers with the information they need to decide which resources work best in their epidemiological and geographical settings. The Policy Relevant Outcomes from Validating Evidence on Impact study (PROVE IT) was set up to evaluate the impact of rolling out promising new diagnostic tools; these include line probe assays in Brazil, Russia, and South Africa, and GeneXpert® in Brazil and South Africa.

Line probe assays simultaneously identify tuberculosis and the most common genetic mutations associated with multidrug resistance. This technology can diagnose MDR-TB in just 5 hours, and if implemented successfully, it can substantially reduce the time to diagnosis of MDR-TB and lead to faster initiation of appropriate MDR-TB treatment. Xpert MTB/RIF is a promising new nucleic acid amplification test that rapidly identifies Rifampicin-resistant TB and has the potential to decentralize diagnostic services. Xpert MTB/RIF is a far more expensive tool than current established approaches but is highly sensitive, quicker, and easier to use.

- The study in Brazil evaluated the efficacy and cost-effectiveness of various TB diagnostic options, including GeneXpert and line probe assays. Preliminary data showed that the total implementation cost (health system and patient cost) was cheaper for GeneXpert (when subsidized) than conventional liquid culture method and line probe assay.
- In Russia, the study evaluated the impact of line probe assays on the time for the identification and treatment of MDR-TB patients in both the civil sector as well as the penitentiary system using data from previous years as baseline. Data showed that the use of line probe assays for MDR-TB diagnostics resulted in a shortened time to diagnosis (from 58 to 24 days), better treatment outcomes, and cost savings for patients.

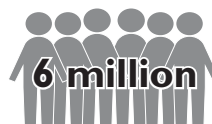
## IN TUBERCULOSIS TREATMENT

WHO issues recommendations and principles on the involvement of communities in TB care and treatment.

The current TB treatment recommendation to use fixed-dose combination are confirmed because it is safe and effective for initial treatment of pulmonary TB and should aid in adherence to early therapy.

2005      2006      2007      2008      2009      2010      2011      2012      2013

A clinical trial evaluated the efficacy, acceptability, toxicity, and treatment outcomes of four-drug, fixed-dose combination tablets versus loose formulations.



Six million people were successfully treated, using fixed-dose combination in the standard 6-month treatment regimen.



- The study in South Africa was set to determine if using the line probe assays was more cost effective than GeneXpert for identifying and initiating treatment for MDR-TB. Data from South Africa showed that the introduction of the new TB diagnosis algorithm resulted in a 25-day reduction in time to initiate treatment for MDR-TB.

USAID supported modeling studies designed to provide policymakers with the information they need to select the most cost-effective diagnostic tools or combination of tools that best improve patient outcomes and limit the transmission of TB in their communities. These modeling studies used a novel approach, known as virtual implementation, which links transmission modeling with operational modeling. Previous modeling studies were built with data from TB patients and programs in Tanzania and Malawi. In this reporting period, the studies were extended to include information from MDR-TB patients from various geographic regions, and these recent studies collected and assessed several diagnostic tools and tests, including line probe assays, Microscopic Observation of Drug Susceptibility and Xpert MTB/RIF among others.

## 2. Treatment Regimens for MDR-TB

USAID continues to implement the STREAM study, which aims to determine whether a standardized 9-month regimen, which has previously been used in Bangladesh with excellent treatment outcomes, can achieve comparable success with slight regimen modifications in different settings. The study is enrolling patients in three countries with the last patient expected to be enrolled in this last quarter of 2014. USAID is building on the STREAM study infrastructure to evaluate the efficacy and safety of a new MDR treatment regimen that will contain the newly FDA-approved TB drug Bedaquiline. The new treatment regimen that will be evaluated will focus on further reducing treatment duration and removing drugs that cause major side effects to patients preventing them from completing treatment.

USAID will also continue to support the evaluation of a number of combination TB treatment regimens with the aim of shortening the treatment of both drug-resistant and drug-susceptible TB. One such regimen combined PA-824, moxifloxacin, and pyrazinamide. It has been evaluated in early clinical trials and has demonstrated that

this three-drug regimen has the potential to treat both drug-sensitive and multidrug-resistant TB, thus significantly shortening TB treatment time. In collaboration with other partners, USAID will support the regimen in a large clinical trial.

## 3. Program Performance and Management of TB-HIV Co-infection

Currently, USAID is supporting 58 operational research projects in more than 13 countries. During this reporting period, nine of these operational research initiatives were completed, and their results were disseminated in countries where they were implemented. One of the studies carried out in Zimbabwe uncovered a delay of 4 weeks between symptoms of TB and the seeking of appropriate medical care. Patients in rural setting were the most affected, and self-medication was a factor associated with that delay. The study called for more interventions to increase patient understanding of TB symptoms and patient awareness of the availability of TB care and treatment services.





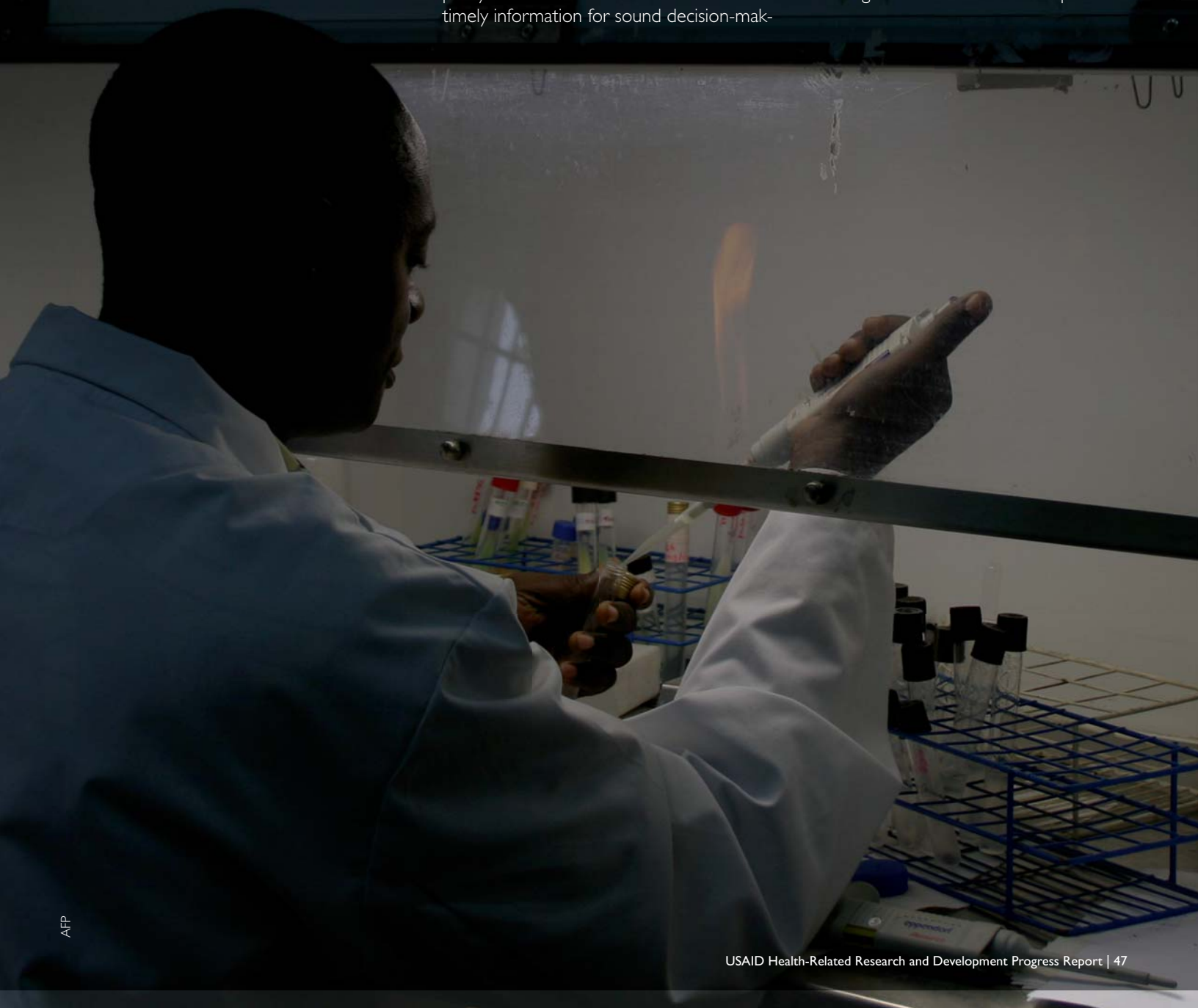
# CROSS-CUTTING ACTIVITIES

This section highlights cross-cutting research activities that support strengthening health systems and scaling for impact. The coordination of these research activities contributes to building a comprehensive and effective evidence base that better informs our thinking and decisions.

USAID invests in health systems research that aims to sustain at scale, the short-term gains of the discrete disease programs, and supports efforts to ensure that policymakers around the world receive timely information for sound decision-

ing. The health systems research portfolio addresses issues around ensuring a strong health workforce, adequate financing, good information systems, and experienced leadership.

USAID established the Center for Accelerating Innovation and Impact to promote innovation and business-minded solutions that support USAID's overarching health objectives by (1) identifying market tools for innovation and acceleration; (2) driving innovation and partnerships; and (3) accelerating introduction and scale-up.

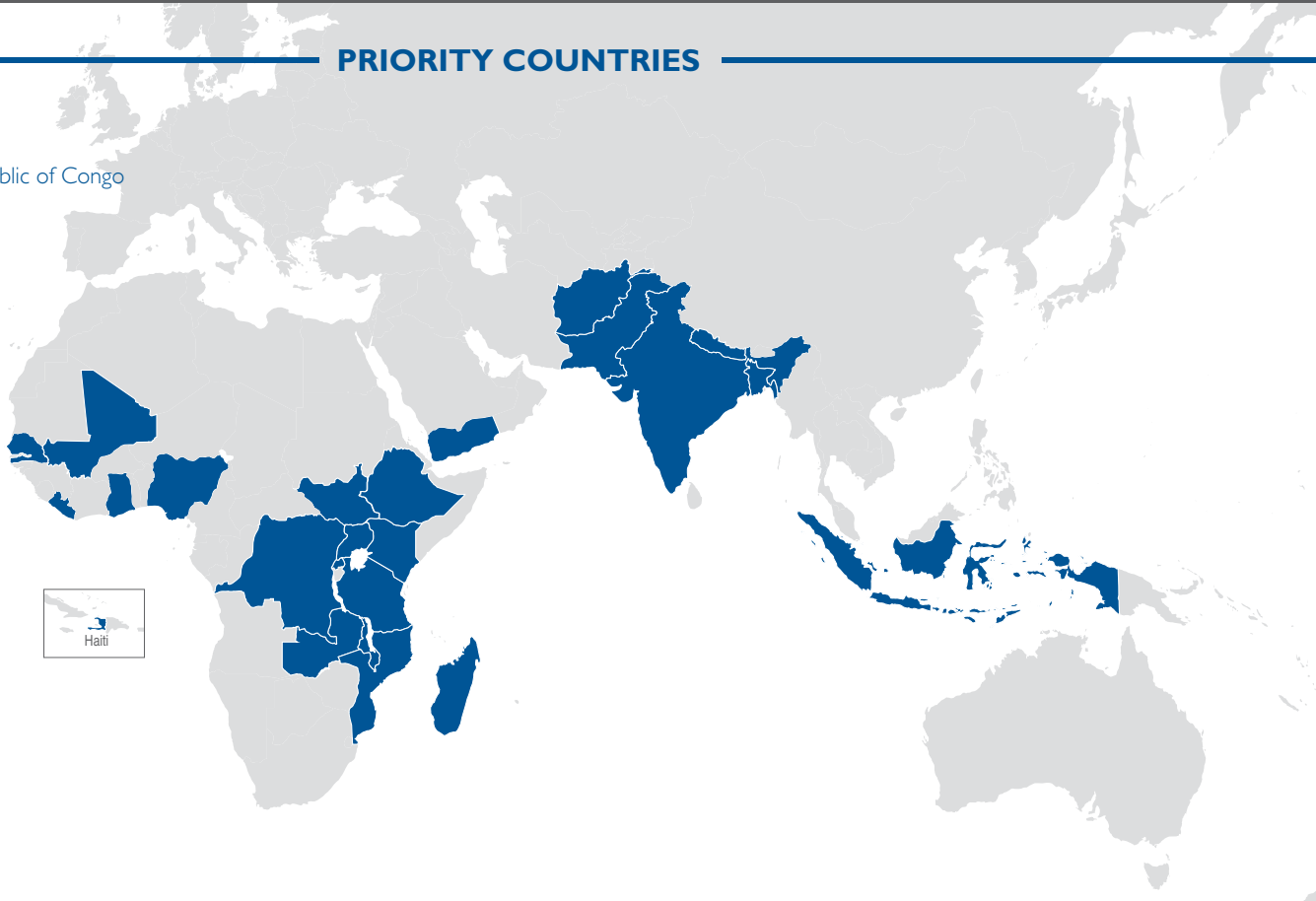


# HEALTH SYSTEMS STRENGTHENING

The World Health Organization estimates that 1 billion people will never encounter a health worker during their lifetimes. A global shortage of adequately skilled, motivated, and supported health workers is partly to blame. The concentration of health workers in urban areas in many countries leaves people living in rural areas without access to quality care. Strengthening health systems involves finding innovative ways to increase the number of high-performing health workers and to ensure the equitable distribution of these valuable resources. Building the capacity of an expanded global health workforce will ensure fewer women and children die from preventable causes.

## PRIORITY COUNTRIES

- Afghanistan
- Bangladesh
- Democratic Republic of Congo
- Ethiopia
- Ghana
- Haiti
- India
- Indonesia
- Kenya
- Liberia
- Madagascar
- Malawi
- Mali
- Mozambique
- Nepal
- Nigeria
- Pakistan
- Rwanda
- Senegal
- South Sudan
- Tanzania
- Uganda
- Yemen
- Zambia



## USAID RESEARCH INVESTMENTS IN

Joint Learning Initiative Report, *Human Resources for Health: Overcoming the Crisis*, described the role of the health workforce in creating and sustaining effective and efficient health systems and identified the global deficit in human resources for health as a key barrier to health systems strengthening.

The First Global Forum endorsed the *Kampala Declaration and Agenda for Global Action*, a historic roadmap laying out key actions required at international, regional, national, and local levels to reduce the HRH deficit over the next 10 years.

2003

2004

2005

2006

2007

2008

World Health Report *Working Together for Health* provided an expert assessment of the crisis in the global health workforce, revealing an estimated shortage of 4.3 million doctors, nurses, midwives, and support workers worldwide and established proposals to build countries' HRH capacity over the next 10 years.

 **iHRIS** iHRIS, an open source software suite that enables users to implement customizable information systems for workforce planning, training and licensure, and management is introduced. Today, iHRIS supports more than 950,000 health workers in 19 countries.

## HEALTH RESEARCH GOALS

To support evidence-based practices that will lead to stronger health systems, we are committed to:

- **Strengthen and improve health systems performance and contribute to more sustainable programmatic outcomes.**
- **Advance methodologies to measure health systems strengthening and performance.**

## BACKGROUND

USAID's health systems research activities identify cost-effective, creative solutions to systemic problems of health system performance. The primary focus of the research is how health systems in low- and middle-income countries organize and provide a comprehensive package of essential services to their populations in an equitable manner and a patient-centered way while preventing impoverishment to clients and their families. The portfolio includes a range of country-level investigations and the development of methods, tools, and metrics that permit measurement of health systems strengthening processes and effects for discrete functions of the health system yet with broadband, system-wide implications.

## I. Strengthening Health System Performance and Evidence-Based Practices

### *Service Coverage and Quality*

As a part of Ethiopia's healthcare financing reform efforts, an assessment is being conducted on the performance and effects of health facility governance boards. The focus is on the extent to which they understand health sector priorities and incorporate issues related to women and girls and community participation into their board agendas and decisions.

USAID is supporting an economic evaluation in the Ukraine that compares the costs and benefits of providing integrated HIV testing and treatment at primary healthcare centers with a current vertical provision model based on specialized trust/AIDS centers.

Additionally, in Uganda, USAID is supporting studies on the effectiveness and efficiency of integrated service delivery to HIV-positive mothers and their babies, as well as a study to explore the factors that influence Village Health Team productivity and performance. In Tanzania and Zambia, field work on two costing studies is examining the efficiencies of the integration of HIV and family planning services, and is further exploring the impacts of service integration on various operational aspects (such as human resources and infrastructure and cost). And in Liberia, the effect of integrating family planning into immunization services is being assessed.

USAID has supported the adaptation of modern quality improvement approaches for use in LMICs, with evidence of impact. The economic benefits of this strategy, however, have not been fully assessed. A study to address the cost-effectiveness of a quality improvement collaborative for obstetric and newborn care in Niger was recently published in the peer-reviewed literature. The authors found that improvements in care reduced the average cost of a delivery from US\$35 to US\$28. The incremental cost-effectiveness of quality improvement in this case was highly favorable: \$147 per disability-adjusted life year saved. The study predicts that if the Ministry of Health were to implement the intervention on a national scale, it would produce a 50 percent annual return on its investment.

### *The Role of the Health Workforce*

The results of a year-long, USAID-led evidence synthesis on strategies to enhance the performance of community health workers are being disseminated through a widely available report, the peer-reviewed literature, and the Third Global Symposium on Health Systems Research. The findings from a similar evidence synthesis exercise, which demonstrated that financial incentives can increase the quantity and improve the quality of maternal health services as well as address health systems issues and financial barriers, are being disseminated this year through the peer-reviewed literature.

## HUMAN RESOURCES FOR HEALTH (HRH)



Third Global Forum on Human Resources for Health is held in Recife, Brazil, under the patronage of the Government of Brazil, the World Health Organization and Pan American Health Organization. A major forum outcome was The Recife Declaration, which was a renewed commitment to workforce development and universal health coverage.

2009

2010

2011

2012

2013

2014

Lancet Commission on Education of Health Professionals in the 21st Century, published *Health Professionals New Century: Transforming Education to Strengthen Health Systems in an Independent World*, which established the need for transformative education as a global priority.



Working with WHO and the Global Health Work Alliance, USAID is co-leading a consultation to help prioritize HRH globally.

### **Access to Medicines and Other Commodities**

To understand the drivers and constraints to supply chain performance in Mozambique and eventually to strengthen the supply chain, USAID has supported a process evaluation of an innovative scheme to incentivize performance among staff of the central medical warehouse. Smart program design, effective program implementation, and a good cycle of accountability and empowerment contributed to the successful results of the program, and the evaluation has served to inform future bilateral grants and other initiatives in Mozambique and beyond.

### **Financing**

USAID continues to support the collection and analysis of health financing and expenditure data in Benin, Ethiopia, and Namibia, and the institutionalization of these efforts in India to inform strategies for reducing inequalities and improving health conditions among women, poor, and young populations.

Community-based health insurance schemes are being evaluated in 13 pilot districts and are comparing the results to 4 control districts in Ethiopia. In Nigeria, an impact evaluation on the effects of incentives on micro health insurance enrollment and use of maternal, neonatal, and child health services is being conducted. These

results will provide much-needed, rigorous evidence quantifying the impact of health insurance on health outcomes in low-income contexts. USAID also is supporting the development of case studies on community-based health insurance in Ethiopia, Ghana, and Senegal. Various evaluations and case studies on community-based health insurance in Africa have informed government efforts to extend these schemes to additional districts, and these will provide lessons and insights on insurance linkages to national health financing frameworks for other countries.

USAID is assisting Indonesia and Myanmar as they adopt implementation research to promote continuous learning and on-the-spot problem solving to advance their respective universal health coverage agendas. Case studies in Ethiopia, Cote d'Ivoire, and Senegal are documenting progress toward universal health coverage goals in each country. Case studies in other countries are examining government capacity to generate and monitor a set of proposed universal health coverage indicators that WHO is considering for global use.

### **Demand and Utilization of Health Services**

In Kenya, USAID is helping carry out a process evaluation of a smartcard that helps women save for pregnancy expenses

and access maternal care – demonstrating which matters facilitate and impede savings and which factors influence a woman's choice of providers. A discrete choice experiment in Bangladesh is assessing facility factors that influence demand for maternal, neonatal, and child health, and family planning services offered by an NGO network. USAID uses Demographic and Health Survey data to produce special population health analyses and trend reports that describe the range of essential health services used by different socio-economic groups in different countries. These analyses shed light on health system performance and change over time. Case studies on improved equity in access and utilization of maternal, neonatal, and maternal health services are being developed in Kenya, Tanzania, Guatemala, and Indonesia. Madagascar is developing a case study on the opportunities and challenges of mobile money and vouchers.

The removal of user fees for health services has been proposed as a means to increase access to maternal and neonatal health services, reduce impoverishment and reduce mortality. User fees, however, can be an important source of revenue for health facilities in resource-poor settings. USAID conducted a synthesis of the literature to identify the effects of user-fee exemptions on the use, provision, and outcomes of



AMY COTTER/USAID



maternal health services. The authors of this research recommended linking user fee exemption policies to the replacement of lost revenue and broader work to strengthen health systems.

## **2. Measurement Tools**

USAID invests in identifying, strengthening, and refining measures of health system strengthening and accompanying instrumentation. For example, the Agency is currently supporting work on a compendium of indicators to measure and track performance on health system strengthening at the program level. In addition, USAID supported the development of a framework to inform a global dialogue on the selection of metrics to measure country progress toward universal health coverage goals. The investment in measurement tools cuts across the following functions:

### ***Human Resources for Health***

USAID is supporting the development of an open-source toolkit to help countries rapidly estimate the cost of health worker retention strategies at district, regional, and national levels. The toolkit, which is being piloted in Laos and Uganda, provides cost

figures to help stakeholders determine the feasibility of various combinations of health worker retention interventions and to budget for the implementation of a broader retention strategy.

### ***Information***

USAID has supported the development of Performance of Routine Information Management (PRISM), a framework and set of tools for routine health information systems. PRISM has helped identify technical, behavioral, and organizational factors that affect information system performance. The PRISM framework has also contributed to the design of priority interventions that can improve the performance of routine health information systems and has improved the quality and use of routine health data in Rwanda.

### ***Human Resource Data Management***

USAID supports the continuing development and use of the Human Resource Information System in 19 countries. This open-source software allows countries to capture and maintain high-quality information for health workforce planning, management, and training. Human Resource

Information System lends itself to rapid adoption by a diversity of stakeholders and promotes both country ownership and sustainability.

### ***Financing***

USAID is supporting development of the National Health Accounts Production Tool, which is currently undergoing user-testing and refinement. Done in collaboration with WHO, this software was developed to streamline the process, including usability enhancements and added functionality. USAID is also supporting a comprehensive review and the development of a framework on alternative and innovative financing approaches for the health sector. USAID continues to provide leadership in developing a global consensus on producing and using resource tracking data for health policy, including harmonization of resource tracking methodologies.

# CENTER FOR ACCELERATING INNOVATION AND IMPACT

*Time and again, specific scientific, technological, and operational breakthroughs have transformed insurmountable development challenges into solvable problems.*

## BACKGROUND

The process of introducing and scaling global health solutions can be complex, lengthy, and resource-intensive. Challenging markets and increasingly constrained budgets make coordination and efficient execution critically important. Whether incorporating user research into a compelling target product profile, executing a coordinated global clinical trial, developing an effective demand generation campaign for specific user segments, or convincing busy country-level advocates and regulators of the value of a new approach, there is no shortage of potential activities that must be considered, prioritized, and addressed.

To tackle these challenges, USAID established a center of excellence in the Global Health Bureau to accelerate the development, introduction and scale-up of priority global health interventions. USAID's Center for Accelerating Innovation and Impact (CII) applies business minded approaches to the development, introduction, and scale-up of health interventions to accelerate impact

against the world's most important health challenges.

## RESEARCH ACTIVITIES

To further these goals, CII has developed a Guide to Introduction and Scale that consolidates and shares best practices and lessons learned from decades of scaling global health solutions and drawing on best practices from the private sector:

The Center is applying these approaches to priority health innovations in support of advancing the Bureau's priorities on achieving an Aids-Free Generation and Ending Preventable Child and Maternal Deaths. In the effort, the Center is partnering closely with technical colleagues across the Bureau to develop and implement launch strategies for priority commodities, including chlorhexidine, microbicides, injectable antibiotics, oral rehydration solution/zinc, amoxicillin DT, and family planning solutions.

CII catalyzes and infuses innovation and partnerships to accelerate priority global

health interventions across the Bureau. Through Saving Lives at Birth: A Grand Challenge for Development, USAID and its partners – the Government of Norway, the Bill & Melinda Gates Foundation, Grand Challenges Canada, and the U.K. Department of International Development – USAID harnesses the collective imagination and ingenuity of global problem-solvers to develop groundbreaking innovations to meet pressing challenges in maternal and neonatal health. The Saving Lives at Birth program supports innovations to proof-of-concept as well as invests in transformational ideas that have the potential to scale up and sustain impact over time (see page 53 and 54 for examples). USAID also collaborates with the National Institutes of Health on the Partnership for Enhanced Engagement in Research (PEER) Health Child Survival program to help end preventable child deaths in developing countries.

Through Saving Lives at Birth, USAID, along with its partners, have been supporting in-

## USAID RESEARCH INVESTMENTS IN BCPAP



A group of bioengineering students at Rice University design the bubble Continuous Positive Airway Pressure (bCPAP).

2009

2010

2011

Saving Lives at Birth Grand Challenges for Development is launched by USAID in partnership with the Government of Norway, the Bill & Melinda Gates Foundation, Grand Challenges Canada, and the U.K.'s Department for International Development.

novative solutions to address long-standing global health challenges. Acute respiratory infections, for example, are the leading cause of global child mortality. Moreover, conditions associated with premature birth, often related to breathing problems, are responsible for an additional 30 percent of infant deaths. In the developing world, oxygen therapy is often the only treatment for babies suffering from respiratory

distress. Without the added pressure of bubble Continuous Positive Airway Pressure (bCPAP), babies struggle to breathe and can suffer serious complications, and frequently death. However, at \$6000, these devices come at a price that is far too expensive for resource poor settings. To address this challenge, a group of students from Rice University invented a novel, rugged, and low-cost bCPAP device to assist

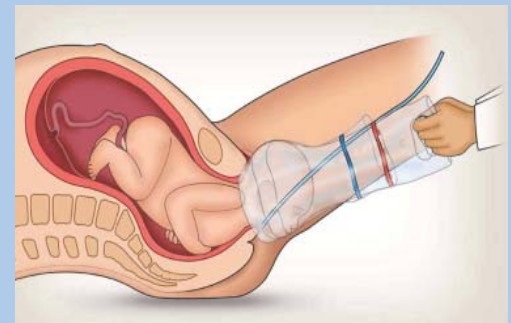
babies suffering from respiratory difficulties. Saving Lives at Birth is providing support of the development and scale-up of Rice's bCPAP. Scaling bCPAP to hospitals across Africa could save the lives of an additional 178,000 neonates each year. CII will continue working with Rice and the manufacturer of this device to support planning for its rapid introduction and scale-up across priority maternal and child health countries.

## THE ODON DEVICE

The Odon Device is the first new obstetrical instrument in decades for assisting vaginal births during prolonged or distressed labor. In 2013, nearly 300,000 women died during and following pregnancy and childbirth with 99 percent of deaths occurring in developing countries. Almost all (90 percent) of these deaths are believed to be preventable. Moreover, for every maternal death, approximately 20 women suffer severe illness, injury, or disability.

Obstructed and prolonged labors are among the top drivers of maternal mortality worldwide, yet until now, only three types of assistance have been available: forceps, vacuum extractors, and cesarean sections. These all bear degrees of risk for mother and child, especially in developing country contexts.

Inspired by a YouTube video on how to extract a cork from a wine bottle with a plastic bag, Argentine auto mechanic Jorge Odon designed a device to assist with birth. The device – comprising a plastic bag and an applicator – uses the same phenomenon of a partially inflated plastic bag to grasp the baby's head and quickly and safely pull it out. USAID and its partners are supporting the Odon Device with a seed grant of \$250,000 through the Saving Lives at Birth Grand Challenge for Development. The World Health Organization is testing the device in Argentina and South Africa, and the U.S.-based firm Becton Dickinson, a leading global medical technology company, has licensed the technology. Becton Dickinson plans to produce and launch the device in 2018 as part of its new business venture into global maternal and newborn health.



CII and Becton Dickinson are partnering together to look at opportunities and challenges in introducing the Odon Device in developing countries and settings, including the Ethiopian market, which accounts for more than a tenth of maternal mortality in sub-Saharan Africa. By expanding access to safe deliveries for both mothers and newborns, the Odon Device has the potential to save thousands of lives.

## TO TREAT RESPIRATORY DISTRESS

In January, the Rice bCPAP team participates in the Saving Lives at Birth Xcelerator program. The program provides training and coaching to Saving Lives at Birth grantees to increase the likelihood that their innovations will succeed. The training prepares innovators to address the complexities of implementing new technologies in the developing world, helping speed up the process by which their ideas are turned into products that can have a real impact and potentially save lives.

More than 700 babies have been treated with bCPAP, potentially saving more than 150 newborn lives in Malawi. Scale-up of bCPAP across Africa could mean that more than 178,000 babies are saved each year.

2012

The device is one of 21 projects selected by Saving Lives at Birth for seed grant funding of \$250,000 to implement a clinical trial of the bCPAP device at Queen Elizabeth Central Hospital. BCPAP is also chosen by the United Nations as one of 10 "Breakthrough Innovations that Can Save Women and Children Now."

2013

In July, Rice University is awarded a \$2 million Saving Lives at Birth transition-to-scale grant to take bCPAP to scale in Malawi.

2014



# INNOVATION LEADS TO GRAND SOLUTIONS

Innovation in technology, service delivery, and demand creation can be a significant driver of USAID's global health program success. Saving Lives at Birth: A Grand Challenge for Development, a USAID partnership with the Government of Norway, the Bill & Melinda Gates Foundation, Grand Challenges Canada, and the UK Department for International Development, calls on the brightest minds across the globe to develop groundbreaking prevention and treatment approaches for pregnant mothers and newborns during the vulnerable hours surrounding birth. Since 2011 and after 4 years of awards, the portfolio supports the development of 81 novel technologies and solutions for use in low-resource settings. In the most recent round of awards, USAID and partners nominated 30 (26 seed grants and 4 transition-to-scale agreements). Potentially transformational, these innovations can help to overcome obstacles typically faced as we aim to reach the most vulnerable, such as lack of one or more of the following: electricity in health facilities to keep medicines and vaccines stable; quality assurance of medicines; transportation to health clinics; and accurate and timely screening tools and diagnostics.

Another Saving Lives at Birth innovation involves scale-up of the uterine balloon tamponade (UBT) as part of a best-evidence package of training, commodities, and checklists related to the treatment of postpartum hemorrhage. The UBT system will also include cutting-edge cell phone technology that will facilitate UBT referral tracking and documentation of patient outcomes. Successful scaling of UBT in these countries will lead to its expansion in other sub-Saharan African countries as well as in other parts of the world.

Taking into account that substandard and counterfeit medicines account for \$75 billion of a \$962 billion global pharmaceutical market and more than 100,000 preventable deaths annually, Saving Lives at Birth supports the development of PharmaChk, a substandard and counterfeit medicines rapid detection and screening platform. This device is a user-friendly, accurate, and high-throughput device capable of quantitatively measuring active ingredient concentration and drug dissolution to quickly screen for spurious medicines. PharmaChk addresses existing shortcomings through quantitative, affordable luminescence and dissolution testing, allowing for highly specific measurements of drug release.

Other examples of the scientific and technological maternal health advancements include projects designed to reduce mortality by family planning. These include projects on a dedicated IUD inserter for postpartum use with the goal of increasing uptake in India and the creation of a low-cost, reusable IUD inserter to eliminate the need to use four separate insertion instruments, making the procedure simpler, safer, and intuitive. These innovations will have a major impact on maternal health by addressing a major gap in access to IUDs, a very effective contraceptive option.



The PharmaChk portable device can be used to rapidly screen for substandard medicines.

DARASH DESAI/ANDREA FERNANDES



# APPENDIX: CORE FUNDING FOR TARGET HEALTH GOALS

Health Area	Health Research Goals	FY 2013 obligated funds	FY 2014 expected funds
<b>ENDING PREVENTABLE CHILD AND MATERNAL DEATHS</b>			
<b>Maternal and Newborn Health<sup>1,2</sup></b>	1. Develop and introduce new and improved evidence-based interventions for care during pregnancy and at birth.	\$1,937,915.00	\$1,229,607.25
	2. Strengthen and standardize high-quality obstetric care for the prevention, management, and treatment of fistula.	\$250,000.00	\$250,000.00
	3. Design, evaluate, and introduce evidence-based interventions to reduce newborn morbidity and mortality from birth asphyxia.	\$259,722.33	\$284,722.33
	4. Develop, test, and introduce community-based health interventions to treat and prevent newborn infections.	\$1,170,000.00	\$1,280,000.00
	5. Develop scalable, cost-effective approaches for integrating maternal and neonatal health services	\$3,555,472.00	\$738,000.00
	6. Assess evidence-based approaches to improve the access and utilization of quality maternal, neonatal, and child health interventions.	\$3,591,574.25	\$1,557,125.00
	7. Develop standardized criteria and effective tools for measuring maternal and perinatal mortality and morbidity.	\$25,000.00	\$47,800.00
	<b>Total</b>	<b>\$10,789,683.58</b>	<b>\$5,387,254.58</b>
<b>Child Health<sup>1</sup></b>	1. Support implementation research to inform the uptake of integrated community case management.	\$724,821.00	\$872,334.00
	2. Develop and test cost-effective approaches to decrease the incidence of acute lower respiratory infections due to household air pollution and injury.	\$109,722.33	\$909,722.33
	3. Evaluate interventions to increase the use of efficacious diarrhea treatments.	\$-	\$250,000.00
	4. Develop and test scalable approaches to improve drinking water quality and access, use of sanitation, and hygiene behaviors.	\$315,800.00	\$979,000.00
	<b>Total</b>	<b>\$1,150,343.33</b>	<b>\$3,011,056.33</b>
<b>Nutrition<sup>1</sup></b>	1. Strengthen and expand the evidence base on integrated multi-sectoral approaches to improve nutrition outcomes, including stunting and maternal and child anemia.	\$1,767,851.00	\$2,072,459.00
	2. Support implementation research for improved diet diversity and quality.	\$2,751,744.00	\$2,901,874.00
	3. Develop, refine, and expand use of state-of-the-art measurement tools for nutrition programs and policies.	\$1,672,835.00	\$1,675,874.00
	<b>Total</b>	<b>\$6,192,430.00</b>	<b>\$6,650,207.00</b>
<b>Family Planning and Reproductive Health</b>	1. Refine, develop, and introduce new contraceptive methods.	\$9,270,000.00	\$7,400,000.00
	2. Improve and expand the use of family planning methods and develop models to increase the healthy timing and spacing of pregnancies in developing countries.	\$10,813,000.00	\$11,535,000.00
	<b>Total</b>	<b>\$20,083,000.00</b>	<b>\$18,935,000.00</b>

<sup>1</sup> These funding levels include both core and field support for centrally managed research projects.

<sup>2</sup> Several research activities that were obligated funding for FY 2013 will come to a close in FY 2014. Until future introduction plans are finalized, the FY 2014 expected funding levels for Health Systems Strengthening and Maternal and Newborn Health are lower than their FY 2013 obligated amounts.

Health Area	Health Research Goals	FY 2013 obligated funds	FY 2014 expected funds
<b>ENDING PREVENTABLE CHILD AND MATERNAL DEATHS</b>			
<b>Malaria</b>	1. Develop safe and effective vaccines to reduce morbidity and mortality due to <i>Plasmodium falciparum</i> .	\$2,420,732.00	\$7,100,000.00
	2. Develop effective and affordable medicines for the treatment and prevention of malaria.	\$4,000,000.00	\$4,000,000.00
	3. Develop new, effective insecticides	\$2,000,000	\$2,000,000
	4. Improve malaria control program implementation and impact.	\$5,424,197.00	\$4,835,000.00
	<b>Total</b>	<b>\$13,844,929.00</b>	<b>\$17,935,000.00</b>
<b>AIDS-FREE GENERATION</b>			
<b>HIV and AIDS</b>	1. Develop and introduce microbicides for women to reduce their risk of HIV infection.	\$42,807,640.00	\$45,000,000.00
	2. Accelerate the development and clinical testing of novel HIV vaccine candidates.	\$27,319,774.00	\$28,710,000.00
	3. Strengthen the evidence base to improve HIV and AIDS prevention, care, and treatment programs.	\$13,508,974.00	\$14,000,000.00
	<b>Total</b>	<b>\$83,636,388.00</b>	<b>\$87,710,000.00</b>
<b>PROTECTING COMMUNITIES FROM INFECTIOUS DISEASES/GLOBAL HEALTH SECURITY AGENDA</b>			
<b>Tuberculosis</b>	1. Develop diagnostic tools to more effectively detect TB in individuals with and without HIV.	\$7,808,336.00	\$12,400,000.00
	2. Develop shorter TB regimens that are effective against all forms of TB, can be used with antiretroviral therapy, are suitable for children, affordable, and easily managed in resource-limited settings.	\$538,156.00	\$1,000,000.00
	3. Conduct operations research for improving TB program performance and management of TB-HIV.	\$1,341,615.00	\$577,000.00
	<b>Total</b>	<b>\$9,688,107.00</b>	<b>\$13,977,000.00</b>
<b>Global Health Security and Development</b>	1. Develop and introduce surveillance methods to increase pathogen detection.	\$7,000,000.00	\$7,000,000.00
	2. Develop and test methods to improve the understanding of risk, including how human behavior contributes to the risk of disease emergence.	\$5,000,000.00	\$5,000,000.00
	<b>Total</b>	<b>\$12,000,000.00</b>	<b>\$12,000,000.00</b>
<b>CROSS-CUTTING ACTIVITIES</b>			
<b>Health Systems Strengthening<sup>1,2</sup></b>	1. Strengthen and improve health systems performance and evidence-based practices that contribute to more sustainable programmatic outcomes.	\$9,252,901.45	\$3,172,439.67
	2. Advance methodologies to measure health systems strengthening and performance.	\$12,249,618.45	\$3,895,324.67
	<b>Total</b>	<b>\$17,968,355.45</b>	<b>\$5,462,074.67</b>
<b>Total Funding</b>		<b>\$175,353,236.36</b>	<b>\$169,067,592.58</b>

<sup>1</sup>These funding levels include both core and field support for centrally managed research projects.

<sup>2</sup>Several research activities that were obligated funding for FY 2013 will come to a close in FY 2014. Until future introduction plans are finalized, the FY 2014 expected funding levels for Health Systems Strengthening and Maternal and Newborn Health are lower than their FY 2013 obligated amounts.

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